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 • Clinical Development Services Agency (CDSA) • Prashanti Cancer Care Mission (PCCM)
Co-Sponsored / Supported by	• Biotechnology Industry Research and Assistance Council (BIRAC) • KEM Hospital, Pune
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, NGOs, Non-profit Organizations, MSMEs, CDSA Alliances, BIRAC supported start –ups, Government Agencies, Individual	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.

o 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

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Workshop Outline

Time (hrs)	Topic and Contents	Venue	Faculty
	Workshop 1: 27 Sept 2016		
0830-0900	Registration	IISER	
0900-0915	Welcome and Introduction to the workshop	IISER	C B Koppiker
0915-1000	Overview of GCP • What is GCP; Why GCP? • Principles of GCP • Guidelines (CDSCO, ICH & WHO)	IISER	Pawandeep Kaur Dhawan
1000-1045	Current Regulations & Guidelines in India for Clinical Trials		A. B. Ramteke
1045-1115	Group photograph and networking tea		
1115-1200	Ethical Considerations • EC functioning • Informed Consent Process • Confidentiality and Privacy • Vulnerable Population		Nandini K. Kumar
1200-1230	Requirements of Clinical Trial Documentation: Protocol, IB, ICF, CRF, CSR		Pawandeep Kaur Dhawan
1230-1300	Record Keeping and Data Handling		Monika Bahl
1300-1400	Lunch		
1400-1445	Roles and Responsibilities of Sponsor		Viraj Suvarna
1445-1515	Roles and Responsibilities of Monitor		Monika Bahl
1515-1600	Roles and Responsibilities of Investigator		Ashish Bavdekar
1600-1615	Tea/Coffee		
1615-1645	Quality Assurance		Sucheta Banerjee Kurundkar
1645-1715	• Exit Assessment • Feedback		All faculty
1715-1730	Open Forum for Q & A and Distribution of Certificates		
	Workshop 2: 28 Sept 2016		
0830-0915	Registration	IISER	
0915-0930	Welcome and Introduction to the workshop	IISER	L S Shashidhara
0930-1030	ICMR Ethical Guidelines for Biomedical	IISER	Vasantha Muthuswamy
1030-1115	Regulations and Guidelines specific to Ethics in India: Schedule Y; Good Clinical Practice		A. B. Ramteke
1115-1145	Group photograph and networking tea		
1145-1230	Ethics Committee		Sanjay K Juvekar

	• Composition • Roles & Responsibilities of Members • Functioning (SOPs, Checklists, Types of Reviews, Monitoring)		
1230-1315	Ethics Committee • Decision Making & Review Process • Risk Benefit Assessment, Communication (Reporting timelines, Communications to Investigator, DCGI, Response to Subject, etc.)		Nandini K. Kumar
1315-1400	Lunch		
1400-1500	Informed Consent Process • Importance • Safeguarding: Volunteers & vulnerable groups • AV recording		Vasantha Muthuswamy
1500-1600	SAE Reporting Timelines, Causality Assessment and Compensation		Y K Gupta
1600-1615	Tea/Coffee		
1615-1715	ICMR-DBT National Guidelines for Stem Cell Research		Nandini K. Kumar
1715-1745	• Exit Assessment • Feedback		Sucheta Banerjee Kurundkar
1745-1800	Open Forum for Q & A and Distribution of Certificates		
	Workshop 3: 29 Sept 2016		
0830-0915	Registration		
0915-0930	Welcome and Introduction to the workshop		V Premnath
0930-1115	Medical Devices and its Draft Bill – Indian Regulatory Scenario Introduction to CDSCO, its structure with respect to Medical Devices. Regulations for import, manufacture and sale of Medical Devices		TBA
1115-1130	Group photograph and networking tea		
1130-1215	Regulations for IVD Kits & Role of NIB in testing		TBA
1215-1315	Classifications of Medical Devices – Comparative Analysis		Malay Mitra
1315-1400	Lunch		
1400-1445	Design and Development of Medical Devices		TBA
1445-1530	Medical Device: Clinical Trial & Biocompatibility		TBA
1530-1600	Industry perspective on current & future regulations		TBA
1600-1615	Tea/Coffee		
1615-1645	Medical Device Standards: CE Certifications & ISO 13485		TBA
1645-1745	Meet the Regulators		Moderator: A B Ramteke

1745-1800	Open Forum for Q & A and Distribution of Certificates		

Speakers and Lecture Faculty (in alphabetical order of last names)	
 Monika Bahl	Monika is Director, Clinical Portfolio Management at CDSA. A graduate in medicine with additional specialization in human resource management, she brings with her over 16 years of experience in clinical practice and clinical research including project planning, clinical monitoring and project management for in-house and outsourced clinical research projects. She has substantial experience of managing projects in varied therapeutic indications including immunology, pain management, cardiovascular, respiratory, dermatology, psychiatry and diabetes mellitus in previous assignments in Indian and global pharmaceutical / Biotech industry (Ranbaxy Research Laboratories, Dabur Research Foundation, Panacea Biotec, Quintiles). She has been associated with clinical studies in paediatric, adult and geriatric populations including mega-trials for DCGI/FDA/BfArM submissions. Her responsibilities have spanned from project planning, protocol designing, CRO selection and project management for the full duration of studies from pre-trial to project close-out, medical monitoring, data review and related medical writing. She has significantly contributed to training and mentoring programs for performance improvement and for quality management initiatives on individual, project and organizational level.
 Ashish Bavdekar	Ashish is Associate Professor, Consultant Pediatric Gastroenterologist, Dept. of Pediatrics, K.E.M. Hospital, Pune. He completed his MD in Pediatrics from B J Government College, Pune. He has been part of several vaccine clinical trials related to pediatric population such as Rotavac vaccine to name a few in collaboration with KEM Hospitals.
 Pawandeep Kaur Dhawan	Pawandeep is Associate Medical Director at CDSA. A post graduate in Medicine (MD, Pharmacology) she has over 10 years of experience in professing clinical research, clinical practice and as clinical research scientist. She has started her career as Junior resident at Govt. Medical College, Patiala and then as Demonstrator in Anatomy at DMCH, Ludhiana. After her MD in Pharmacology from Govt Medical College, Amritsar; She worked as Clinical Pharmacologist at Escorts Heart Institute and Research Centre, Delhi where she also played a role of member of Institutional Review Board and member secretary of various hospital committees. 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. 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. 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 has been part of the team which was felicitated by Ex-President Dr. APJ Abdul Kalam for her outstanding contribution in development of new drug for malaria. She has 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 and Cochrane Back Review Group (CBRG), Toronto.
 Y K Gupta	Gupta is Professor & Head of Pharmacology, AIIMS, New Delhi. He is also National Scientific Coordinator, Pharmacovigilance Programme of India (PVPI) and Chief of National Poison Information Centre, AIIMS. He has received the excellence award for forensic medicine in 2008. He has been Chairman of the Clinical Medicine and Pharmacology Committee of the Indian Pharmacopoeia Commission since 2006 and has several other honours and awards to his credit. He is also visiting Professor at University of Illinois at Chicago, USA.
 Sanjay K Juvekar	Sanjay is Officer-In-Charge, Vadu Rural Health Program, KEM Hospital Research Center, Pune. He has done his doctorate in Medical Anthropology from University of Pune. He has played a major role in establishing Health and Demographic Surveillance System (HDSS) at Vadu. In addition to this responsibility he was the Principal Investigator on various studies including IMVAC study on COPD in India in collaboration with the CRF, Pune and the Imperial College, London; Non-communicable diseases risk factor study; iShare; Health Equity Study supported by INDEPTH. Currently, he is the Principal Investigator on studies including 'influenza disease burden in India' (IDBI study) in collaboration with NIV, ICMR, and CDC (USA); Study on Ayurveda and genomics supported by IGIB and Co- Investigator on Vaccine trials including Vaccine trial on rotavirus vaccine supported by Department of Biotechnology, India and PATH, USA. He was the Study Manager on aerosol measles vaccine trial supported by ICMR and WHO. Prior to joining VRHP he has worked with the Foundation for Research in Community Health (FRCH) for 8 years in the field of Tuberculosis and behavioral sciences. He has mentored about 30 students in their research and field activities.
 C B Koppiker	Dr. Koppiker is Director, Prashanti Cancer Care Mission, Pune
 Nandini K. Kumar	Dr. Nandini is Former Deputy Director General (Sr. Grade), ICMR, Dr. TMA Pai Endowment Chair, Manipal University; Adjunct Faculty at CDSA. She is a Graduate and Post-graduate in Clinical Pathology from Trivandrum Medical College. She was involved in medical research in the Gastroenterology Department at Trivandrum and at Madras Medical College, Chennai. She also was in charge of the Liver Clinic at General Hospital, Chennai. Having joined the Indian Council of Medical Research (ICMR) headquarters in New Delhi as a senior researcher, she was a Program Officer for Traditional Medicine Research and Bioethics. In this capacity she had been a member of several ICMR national and international working groups and organized several national and international agency-sponsored workshops on ethical issues involving biomedical research and traditional medicine research. She was closely involved with activities related to the Government's Golden Triangle Partnership Scheme related to drug development in traditional systems of medicine and other similar programs in the country concerning herbal or herbo-mineral formulations. She also had been closely involved in finalization of the ICMR Ethical Guidelines of 2000 and of 2006, especially the section on traditional medicine research, and of the Draft Guidelines on Bio-banking and Stem Cell Research and Therapy, Mental Health Research, Data Set Protection and Disaster Related Research. As a member of the

	executive committee of the Forum for Ethics Review Committees in India, a National Chapter of the Forum for Ethics Review Committees in Asia Pacific, she is involved in ethics committee related activities of India. She is also a Fogarty Fellow graduate in bioethics (International Stream), from the University of Toronto.
 Sucheta Banerjee Kurundkar	Sucheta is Director, Training at CDSA since 2012. She has 18 years of experience in various capacities in research & CRO Industry. She started her career from Pune where 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. Sucheta has worked for several years in the area of Quality Assurance in pre-clinical, clinical and medical laboratories and has an avid interest in this area. She is a GLP Trainer (WHO); Auditor for NABL (ISO 15189 & ISO 17025) & NABH. Sucheta has a Ph.D. in Biochemistry from 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 and Management of Training from ISTM, New Delhi. Sucheta is the reviewer to many International Journals of repute. At CDSA, she has been involved in the conduct of 73 training programs across 40 cities covering approximately 5000 participants, 1380 institutions and 749 faculty members till May 2016.
Malay Mitra	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 and was an active member in developing the Schedule M, GMP part of the Drugs and Cosmetic Rules. He represented CDSCO at the Asian Harmonization Working Party conference (China) for medical device. He 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.
 Vasantha Muthuswamy	Dr Muthuswamy retired in 2009, as the Senior Deputy Director General and Chief of the Division of Basic Medical Sciences, Traditional Medicine and Bioethics, and the Division of Reproductive Health and Nutrition, of the Indian Council of Medical Research. She completed her MD in Obstetrics and Gynecology in 1979 and immediately joined ICMR as Research Officer at the Toxaemia Research Unit, Bangalore. She moved to the Institute for Research in Reproduction, Mumbai, in 1980 and to the ICMR headquarters in New Delhi in 1982. She played a major role in the Council's activities in drug development. This work included traditional medicine, genetics and genomics; the ethics of animal and human experimentation; the promotion of research by medical students, and the development of various guidelines to facilitate research in the country. She has been a visiting fellow at the Kennedy Institute for Ethics at Georgetown University, USA, since 1997, which initiated her into the field of Bioethics. Dr Muthuswamy is recognised internationally as the force behind the ICMR's "Ethical Guidelines for Biomedical Research on Human Subjects" in 2000, and then the revised version in 2006, a landmark document, in the country, for guidance on ethics review. She has also developed guidelines for animal experimentation, for stem cell research and therapy, for safety evaluation of food derived from genetically engineered plants, for biobanking, and for good clinical laboratory practices. She has also contributed to the development of research ethics guidelines for other countries, like Nepal and Sri Lanka, and for

	agencies such as the World Health Organization, the Joint United Nations Programme of HIV/AIDS, the Nuffield Council on Bioethics, Family Health International and the HIV Prevention Trials Network. She is a member of many national and international ethics committees. She is currently President of the Forum for Ethics Committees in India. She an untiring teacher and has given more than 500 lectures on bioethics, and on drug development, including some on traditional medicines, on regulation, and on good clinical practice as part of her efforts to educate students and practitioners on bioethics. She has conducted many dozens of ethics workshops for different stakeholders within India, and in more than 25 countries across the world.
 A. B. Ramteke	Mr Ramteke is Senior Consultant for Regulatory Affairs at CDSA. He retired as a senior drug regulatory officer with 31 years of experience in drug regulatory aspects in the office of the Drugs Controller General of India (DCGI). He has in-depth knowledge of Indian Drugs & Cosmetics Act, Rules and of regulations of Global Drug Regulatory norms. He started his career at Central Research Institute Kasauli in biological-drug testing. 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, and quality control, clinical trial data of new drugs, biological and medical devices (INDs, ANDAs). He has strong skills in quality assurance management, regulatory oversight of clinical trials, development of SOPs and guidelines and involvement in drug rules amendments. He has contributed to preparation and implementation of Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and Good Manufacturing Practices. He works as an Expert to the Pharmacovigilance Program, GCP Training and Inspections of CROs in India.
 L S Shashidhara	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.
Viraj Suvarna	Viraj is Medical Director, Boehringer Ingelheim, Mumbai
 Premnath Venugopalan	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	
	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/
	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 (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
	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/

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	Biotechnology Industry Research & Assistance Council is a new industry-academia interface and implements its mandate through a wide range of impact initiatives, be it providing access to risk capital through targeted funding, technology transfer, IP management and handholding schemes that help bring innovation excellence to the biotech firms and make them globally competitive. For more information about BIRAC: www.birac.nic.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