

Biotechnology Industry Research Assistance Council (BIRAC),

Department of Biotechnology
Ministry of Science and Technology
Government of India

National Biopharma Mission



E-BROCHURE for Networks of Clinical Trial Sites in Oncology, Ophthalmology, Diabetology and Rheumatology



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CLINICAL TRIAL NETWORK

National Biopharma Mission is An Industry-Academia Collaborative Mission of Department of Biotechnology (DBT) for Accelerating Early Development for Biopharmaceuticals; to be implemented by Biotechnology Research Assistance Council (BIRAC).

The Mission Programme is a Pan-India Programme with the main aim of making India a hub for design and development of novel, affordable and effective biopharmaceutical products and solutions. This Program would aid in enhancing India’s innovation research and product development capabilities, especially by focusing on development of vaccines, biologics and medical devices for combating public health concerns.

Clinical trial is an important step in the product development path requiring multiple trial sites. Indian Biotech companies face numerous challenges in identifying trial sites which have the required infrastructure, capacity, trained manpower, harmonized processes and background data on disease incidence at institutional, local, regional/state, and national levels. The delay in conduct of clinical trials can impact the development timelines of biologics and drugs and thereby delaying the launch of affordable biosimilars for Indian population.

To address the above, Department of Biotechnology and National Biopharma Mission’s initiative, **Clinical Trial Networks, with Consortia of Hospitals** in the areas of **Oncology, Ophthalmology, Rheumatology and Diabetology, CHOORD** aims to strengthen the capacity to conduct clinical trials in India for products developed in these areas. It comprises of 5 networks of 36 organizations, public and private hospitals, clinics, reputed academic institutions, spread across 18 states of India.

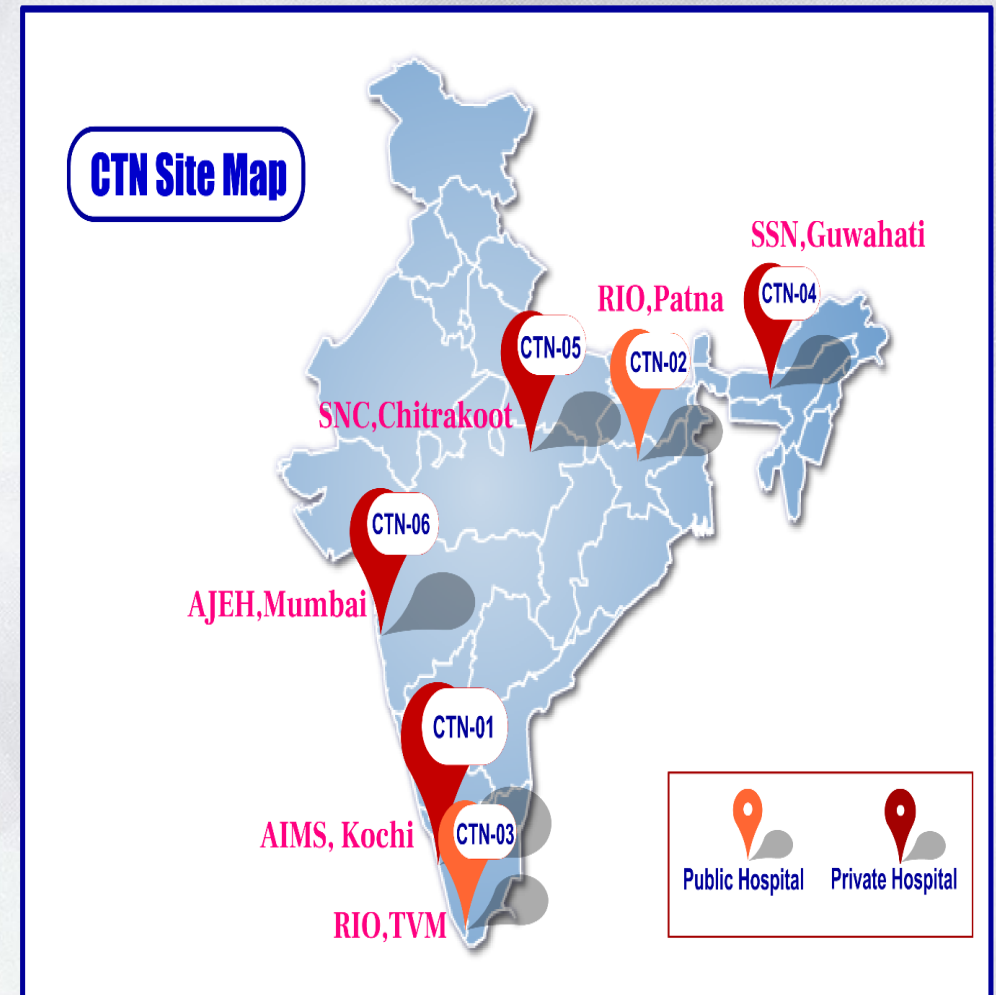
Each specialty network comprises of at least 6 hospital-based investigational sites (public and private hospital sites) across different geographical regions of the country. This e-book captures the information about these 5 networks, with their aim, individual strengths and capabilities with geographical locations of the hospitals and catchment areas



Ophthalmology

The aim is to develop a network of clinical trial centres across Indian both in government and private sector providing high volume tertiary care services in Ophthalmology through the multi central collaboration of academic institutions with Indian industry, to handhold them and bring out some very high quality, innovative Biologicals into the market. The network is a right mix of innovator institutions, high volume centres, rural and backward areas of India and collaborators with immense experience. The Pan India presence includes: the South in Kerala, the health hub of India with two centres, one in government and one in private side. Chitrakoot is one of the highest volume centres in India. Regional Institute of Ophthalmology, Patna and Sri Sankaradeva Netralaya, Guwahati, are the best hospitals in rural and backward part of India. The lead site of the Ophthalmology network is Amrita Institute of Medical Sciences, Kochi, Kerala.

For the first time in India, a solitary Patient Registry “A Hospital-Based Multicentre Registry for common medical retinal diseases” for four diseases (diabetic retinopathy, Age related macular degeneration, retinal vein occlusion and CNVM) is being developed under the clinical trial network collaborated with six other hospitals/institutions which are excellence in the field of Ophthalmology.



Name of the Site

Amrita Institute of Medical Sciences(AIMS), Kochi, Kerala

PI Name:Gopal S Pillai/+919447391266/ gopalspillai@gmail.com,

gopal@ioctn.org

Background of the Site

- The institute is run by a trust Amrita Vishwa Vidyapeetham, a multi-campus; multi-disciplinary research academia collaborated with more than 50 Industrial partners globally since 1998.
- One of the best research institutions in India, accredited 'A' by NAAC and ranked as 4th best university in India (nirf 2020). Ranked No.10 for BEST Ophthalmic Services in the National Ranking conducted by the Times Group on Top All India Lifestyle Hospital & Clinic.
- The site is one of the premier super-specialty quaternary care health centre, has performed the first double arm transplant in Asia and first salivary gland ocular translocation. The centre is First Robotic Surgery Centre with Neuro-immunology laboratory in India.
- One of the pioneers in 25-gauge suiter less retinal surgeries in India.
- First to start OCT imaging and Anti-VEGF treatment in Kerala.

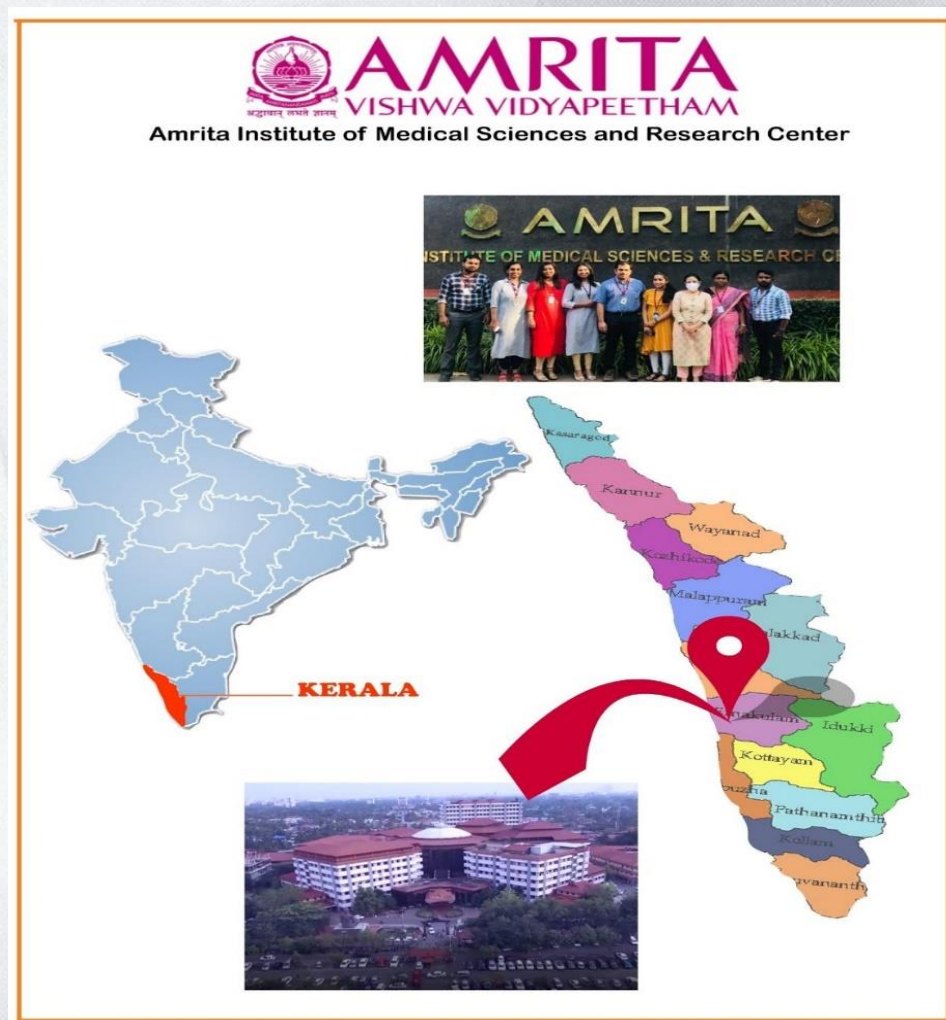
Key Capabilities/Strength

- AIMS and its facilities has accreditation by NABL, NABH, ISO 9001:2008; OHSAS 18001:2007.
- Excellent basic research and Nano sciences infrastructure with Animal house facility along with GA facility, robotic training and 7 Tesla MRI.
- Institutional ethics committee has been registered with CDSCO, DHR and DSIR and conduct IEC meeting in the timeline of twice in every month.
- Twelve staff has been recruited under NBM project (Data entry operators, clinical trial co-ordinator, Quality Manger, Project Manager, Medical officer, Network Administrator, Biostatistician, Accountant and Office assistant) for the project are qualified researchers with GCP certification, also the site is well equipped and facilitated based on ICH-GCP requirements.
- Well experienced in clinical trials – completed 550 intramural projects in last 5 years and 56 extramural projects. Completed three clinical trials in last 5years and two clinical trials currently are ongoing in the department of Ophthalmology.

Geographical Location / Catchment Area (Blowout Map)

Geographical Location: Kochi, Ernakulum District, Kerala, India

Catchment Area: AIMS provide service all around Kerala and South India and some Gulf countries, Maldives, Lakshadweep and many more countries in Africa have MoU and insurance tie ups with Amrita hospital for specialised care for their population.



Name of the Site : Aditya Jyot Eye Hospital Pvt. Ltd (AJEH), Mumbai, Maharashtra

PI: Dr S Natarajan/ +91 9920241419/prof.drsn@gmail.com, drsnatarajan@ioctn.org

Background of the Site

- The hospital is Mumbai's first NABH accredited Eye hospital with more than two decades of services.
- Pioneer in Community Health Research amongst the urban slums of Mumbai.
- First hospital in Asia for: Retinal Endoscope and Preferential Hyper Acuity Perimeter
- First hospital in India for: Constellation Vitrectomy System – 1st Private Hospital in India, Fourier Domain Optical Coherence Tomography - III for Retina, Cornea and Glaucoma, Photodynamic Therapy, Sutureless 25 Gauge in Vitrectomy System for Sutureless Vitreoretinal surgery, BIOM Wet lab and Twilight Endo illumination for Vitreoretinal surgery.
- First hospital in Mumbai for: IOL Master - the revolutionary method for IOL power calculations in cataract surgery AND Fourier Domain Optical Coherence Tomography – III for Retina, Cornea and Glaucoma.
- AJEH has cutting-edge facilities both for basic and advanced diagnostic tests and surgeries like Cataract, Cornea & Ocular Surface, Retina Vitreous Service, Uveitis, Glaucoma, Paediatric Ophthalmology, Neuro Ophthalmology, Genetic Clinic, Orbit Oculoplastic Surgery, Ocular Prosthesis, Diabetic Clinic

Key Capabilities/Strength

- AJEH has a genetic testing lab and a basic research lab and Not for Profit Foundation, Aditya Jyot Foundation for Twinkling Little Eyes which is associated with AJEH and conducts regular eye camps in the urban slums of Mumbai. The foundation has a large database of patients with different eye conditions who can be participants for various clinical studies.
- An eleven-member team is headed by Principal Investigator includes – Medical Officer, Project Manager, Quality Manager, Project Coordinator, Optometrist, Data Entry Operator, Supervisor, Accountant, Office Assistant and Health workers. The entire study team is ICH-GCP and SOP Trained.
- The hospital is having MoU with NABL accredited lab (SRL Labs)
- 15 consultants overseeing various ophthalmology divisions and Clinical Research department which has conducted over 20 trials

Geographical Location / Catchment Area

Geographical Location: Wadala, Mumbai, Maharashtra, India

Catchment Area: catering services in and around 120 km radius distance of the hospital



Name of the Site:

Shri Sadguru Seva Sangh Trust (SSSST), Chitrakoot, Madhya Pradesh

PI: Name: Dr. Alok Sen/ +91 7898201605/ draloksen@gmail.com

drsnatarajan@ioctn.org

Background of the Site

- Shri Sadguru Seva Sangh Trust (SSSST), a humanitarian organization, established in 1968 with the vision: 'Service to Humanity' & the mission: 'Food for the Hungry, Clothes for the destitute, Sight for the Blind'
- Sadguru Netra Chikitsalaya (SNC) is a state-of-the-art Tertiary Eye Care Hospital of SSSST in the rural part of central India Chitrakoot, Madhya Pradesh.
- Over the last 52 years, Sadguru Netra Chikitsalaya has been working towards elimination of curable blindness from the rural areas of central and northern part of India.
- Achieved national and international recognitions for its service delivery, modern ophthalmic practices and its community-oriented reach out activities.
- During the FY 2020-2021 a total of 7,25,848 patients were screened of which 97,501 surgical procedures were performed in the hospital through its direct and reach out services.

Key Capabilities/Strength

- 125+ Ophthalmologist at a single eye care hospital located in a rural setting.
- EC registered with CDSCO.
- Hospital is NABH Accredited and MOU is signed with NABL accredited Lab.
- The facility has 26 modular OT fully dedicated to eye care.
- Total staff strength of more than 700.
- Comprehensive eye care services.
- Backed up with 55 vision centres for primary eye care services .3 city clinics with full time ophthalmologists. Reaching out to the remotest areas of Central India by conducting more than 3500 camps in a single year.
- Dedicated research and training centre

Geographical Location / Catchment Area

Geographical location: Chitrakoot, District Satna, Madhya Pradesh, India

Catchment area: The centre caters to more than 30 districts in the state of Madhya Pradesh & Uttar Pradesh.



Background of the Site

- One of the finest eye care hospitals in North East India located in Guwahati (Assam), established by Sri Kanchi Sankara Health & Educational Foundation and run by Government of India and Government of Assam.
- Provides patient focused state-of-the-art and safe eye care services through dynamic professionalism and cutting-edge technology.
- Provides a comprehensive range of Ophthalmic and Optometric services under one roof.
- A preferred institution for career, education and research, and support services in Ophthalmology and Optometry in the country.
- The site has adopted cluster of 900 villages and has been responsible for 200 blindness free villages (140 declared by Prof. Jagdish Mukhi, Hon Governor of Assam, 38 by Representative from Operation Eyesight Universal, Canada, 10 by Dr. Kumud Lal Saikia, State Programme Officer; SPO (NPCB & VI, Assam).

Key Capabilities/Strength

- SSDN is NABH accredited and has a well-equipped NABL accredited laboratory.
- Eleven qualified & experienced staffs have been recruited under NBM/BIRAC project (Project Manager, Research Officer, Quality Manger, Project Co-coordinator, Data entry operator, Optometrist, Supervisor, Accountant, Office assistant & Health Workers). All staff are trained & certified in Good Clinical Practice (GCP).
- Site is well equipped and facilitated as per ICH-GCP requirements. 2500 sq. feet area has been specifically allotted for the NBM/BIRAC project at site.
- Site is registered with Department of Scientific and Industrial Research (DSIR) and the Institutional Ethics Committee (IEC) is registered with CDSO.
- Site comprises of comprehensive eye examination with state-of-the-art equipment and instruments.
- SSDN has a number of ongoing research projects under DBT, ICMR and other organizations. More than 110 research projects have been completed so far (10 Clinical Trials, 13 Extramural and 87 Intramural projects).

Geographical Location / Catchment Area

Geographical Location: Saurabh Nagar, Beltola Tiniali, Kamrup (M) District, Guwahati, Assam. India

Catchment Area: Catering services throughout North-East India- Assam, Meghalaya, Mizoram, Nagaland, Manipur, Arunachal Pradesh, Tripura and patients from Bangladesh and Nepal.



Name of the Site

Regional Institute of Ophthalmology(RIO), Thiruvananthapuram, Kerala

PI: Name: Dr. Sheeba C S/+91 9446968341/_sheeba.c.s@gmail.com ,
drsheebacs@ioctn.org

Background of the Site

- RIO, Thiruvananthapuram is one of the biggest tertiary eye care centre in South India.
- With a view to provide medical care for eye diseases par excellence in a holistic manner, the Ministry of Health and Family Welfare envisaged to provide assistance for setting up of Regional Institute of Ophthalmology (RIO) in different parts of the Country under National Programme for Control of Blindness.
- RIO, Thiruvananthapuram originated as a government ophthalmic hospital in 1905, and was brought into the National Programme for Control of Blindness in 1995.
- RIO have 24 hrs functioning pharmacy facility and is known for offering excellent patient care.

Key Capabilities/Strength

- Well experienced team of doctors and researchers in ophthalmology to perform at its highest level in all areas of ophthalmology involving clinical sciences, surveys, laboratory and allied sciences are present in the institute.
- Four staff has been recruited under NBM project (Project Manager, Medical officer, Quality Manger, Project Coordinator) and all well qualified researchers with GCP certification, also the site is well equipped and facilitated based on ICH-GCP requirements. Well-equipped clinic with all the modern equipment.
- IEC is CDSCO registered.
- Thousand out-patients per day. The clinic has separate waiting and consultation areas which allow enough space for patients to wait conveniently at the clinic
- Completed 18 clinical trials in last 3 years and 6 clinical trials currently are ongoing

Geographical Location / Catchment Area

Geographical Location: Vanchiyoor, Thiruvanthapuram District, Kerala, India
Catchment Area: RIO provides services across Kerala and Tamilnadu covering around a distance of 600km.



Name of the Site: Regional Institute of Ophthalmology, Indira Gandhi Institute of Medical Sciences (IGIMS), Patna

PI: Name : Prof. (Dr.) Bibhuti Prassan Sinha/ +91 94700 17777/bibhuti13@gmail.com, drbibhuti@ioctn.org

Background of the Site

- IGIMS was established in 1983, as an autonomous organization on the pattern of AIIMS-Delhi.
- IGIMS is spread over 150 acres of land, this is a part of Bihar Gov. Autonomous Institute of Excellence.
- RIO, IGIMS-Patna is apex institute of super speciality eye care in Bihar and started in 1995.
- RIO, one of the best equipped institutes in eastern part of India. Presently 1070 bedded hospital. Construction is ongoing of another 500-bed ultra-modern hospital, 100-bed Regional Cancer Centre, and 200-bed Regional Institute of Ophthalmology.
- RIO, Patna is involved in multiple clinical research trial phase III/IV.
- RIO has received grant of 187 crores for upgradation of project likely to be completed in Aug-Sep, 2022.
- This project plans to develop 5 super specialty department under one roof of 250000 sq. feet of floor area.

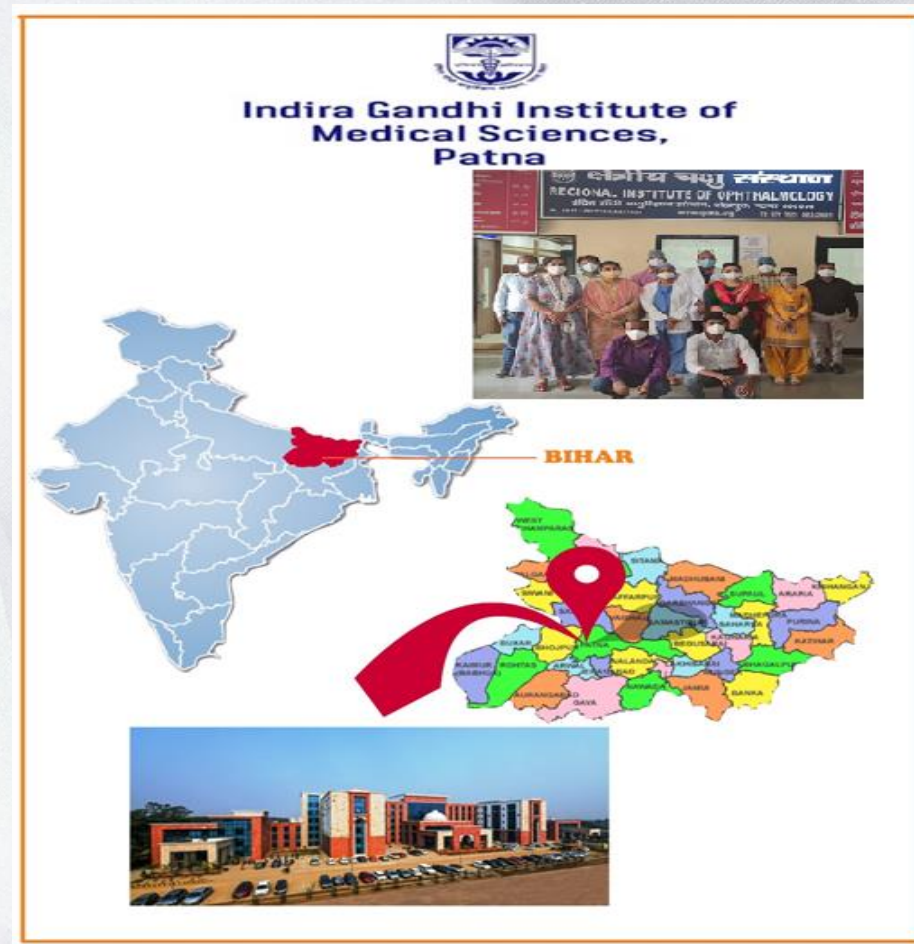
Key Capabilities/Strength

- Approx. one lakhs patient's visit per year at RIO, IGIMS-Patna.
- Fully digitalized patient care, diagnostic, teaching and administrative system
- Has well established Eye Bank of Bihar at RIO as a center of excellence for eye banking in state of Bihar
- RIO, IGIMS has signed MoU agreement with NABL accredited SARAL PATH Lab.
- Promotes and educates public about eye donation.
- Tele-Ophthalmology adopted as regular manner.

Geographical Location / Catchment Area

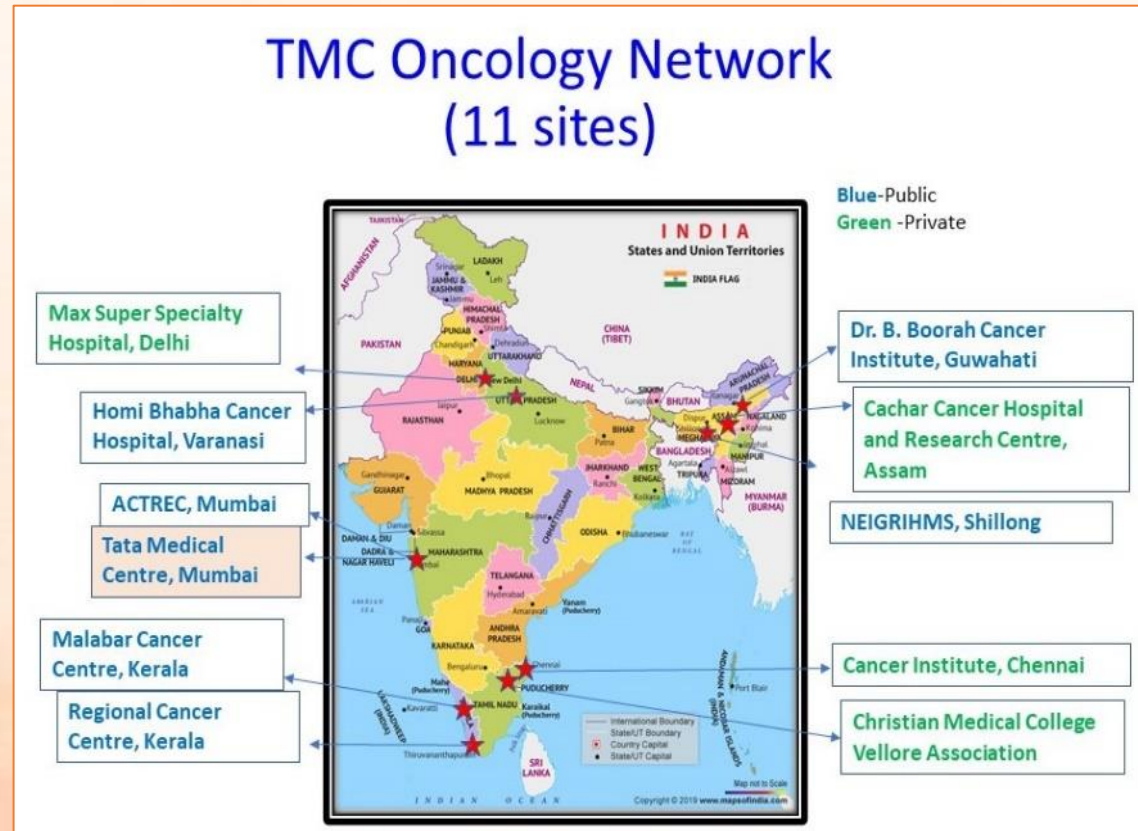
Geographical Location: Patna, Bihar, India

Catchment Area: The institution caters services to patients from Bihar, Nepal, Uttar Pradesh, Jharkhand and West Bengal also serves a population of more than 14 crore individuals



Tata Memorial Centre (Lead Site)

The aim is to build and strengthen a network of clinical trial units within the National Cancer Grid (NCG) to promote multicentric high-quality clinical trials for affordable therapy in oncology, which will enhance the capability for conduct of Industry-sponsored trials of new cancer drugs and biosimilars by : Manpower training and infrastructure development, process harmonization between centres and to conduct collaborative investigator - initiated research. There are 11 sites (7 public and 4 private) in the consortia from different regions under PAN India. Tata Memorial Hospital, Mumbai is Lead site of the multicentric Clinical Trial Network (CTN). Prospective Registry database in Lymphomas, Chronic Myelogenous Leukemia, Colorectal Cancer, Lung Cancer, Gall Bladder Cancer is being created across sites of the network.



Name of the Site: Tata Memorial Centre, Mumbai, Maharashtra
PI: Dr Rajendra A Badwe, Director TMH/22 24177000 extn
131/badwera@tmc.gov.in

Background of the Site

- A comprehensive cancer centre for the prevention, treatment, and research on cancer.
- One of the largest tertiary cancer centres in Asia.
- 45,000+ new patients are registered from all over the India and neighbouring countries.
- State-of-the-art infrastructure and laboratories.
- Pioneered several practice-changing clinical trials – prevention and treatment of cancer.
- Lead centre for the establishment of ready network of clinical trial units across the National Cancer Grid to promote multi-centric collaborative research in drug and device development supported by NBM BIRAC.

Key Capabilities/Strength

- Large pool of patients.
- GCP trained dedicated staff available at site for conduct of clinical trials- multi-centric -investigator-initiated and industry sponsored.
- In-house NABL accredited laboratories.
- Electronic medical records.
- Clinical Research Secretariat with central research pharmacy and workstations.
- Institutional Ethics Committees registered with DCGI - AAHRP and SIDCER accredited.
- In last five years a total 500+ trials were conducted in TMC and 600+ trials in oncology are Ongoing.

Geographical Location / Catchment Area



Name of the Site: Advanced Centre for Treatment, Research and Education in Cancer (ACTREC), Mumbai, Maharashtra

PI: Dr Jayant Sastri Goda/ +91- 9930004414/godajayantsastri@gmail.com

Background of the Site

- The Advanced Centre for Treatment, Research and Education in Cancer (ACTREC) started as the basic research unit of Tata Memorial Centre (TMC) in its erstwhile avatar of Cancer Research Institute (CRI) many decades ago and was located in the vicinity of Tata Memorial Hospital until 2003. ACTREC is now located in a sprawling campus in Navi Mumbai and is also the location of Centre for Cancer Epidemiology
- The core focus of ACTREC remains basic and translational research and is facilitated by the collocation of basic scientists, well equipped laboratories, and clinicians running a high-quality clinical cancer facility.
- The research strategy of ACTREC echoes the very mandate of NCG by encouraging interdisciplinary clinical and translational scientific projects and collaborates both within the Centre and also with national/ international centres of repute from academia and industry.

Key Capabilities/Strength

- Well established infrastructure framework and the highly motivated manpower who are a rare mix of clinical oncologists, basic researchers, clinician scientist trained in translational cancer research and the ancillary staff. GCP trained, experienced and dedicated staff – Biostatistician-01, Project coordinator – 02, Asst. Data Manager – 01 available.
- Clinical trials unit for Implementing clinical trials (investigator initiated and industry sponsored trials).
- Well-equipped and NABL accredited laboratories capable of doing advanced laboratory assays including molecular and cytogenetic assays.
- A dedicated Phase-I clinical trials unit with attached clinical pharmacology lab.
- CDSCO registered IEC, DSMU and ICSR (institutional committee for stem cell research) accredited by the AAHARPP & SIDCER.
- Oncology trials Completed – 11 and ongoing – 29, Registry trial – 01

Geographical Location / Catchment Area

Advanced Centre for Treatment, Research and Education in Cancer (ACTREC)
Sector 22, Utsav Chowk - CISF Rd, Owe Camp, Kharghar, Navi Mumbai,
Maharashtra 410210



Name of the Site : Dr Bhubaneswar Borooah Cancer Institute (BBCI), Guwahati, Assam

PI: Dr Ashok Kumar Das / +91 9954139727 / adas171@yahoo.co.in

Background of the Site

- BBCI, a cancer care hospital and research centre located in Guwahati, eastern city in the state of Assam. The centre is a grants-in-aid institute of Department of Atomic Energy, Government of India, and a unit of Tata Memorial Centre, Mumbai.
- About 12,000 new and 80,000 old cancer patients visit the site every year. It is a 230-bedded Hospital at present.
- There are 100 bedded (general) and one 27 bedded executive guest houses for patients & relatives inside the hospital premises.
- Clinical Research Secretariat was established in Jan 2019.
- The Institute has a Palliative Medicine and Preventive Oncology department. DBT Centre for Molecular Biology and Cancer Research instruments as CFX96 Real Time PCR System, Rotor GeneQ real time PCR system, fully motorized Fluorescence Microscope for FISH, 3X32 Proflex PCR system, Automated DML2000 Hybrid Capture System, CareHPV system, Qubit 3 fluorometer, CO2 Incubator, Class II Biosafety cabinet, Inverted microscope.

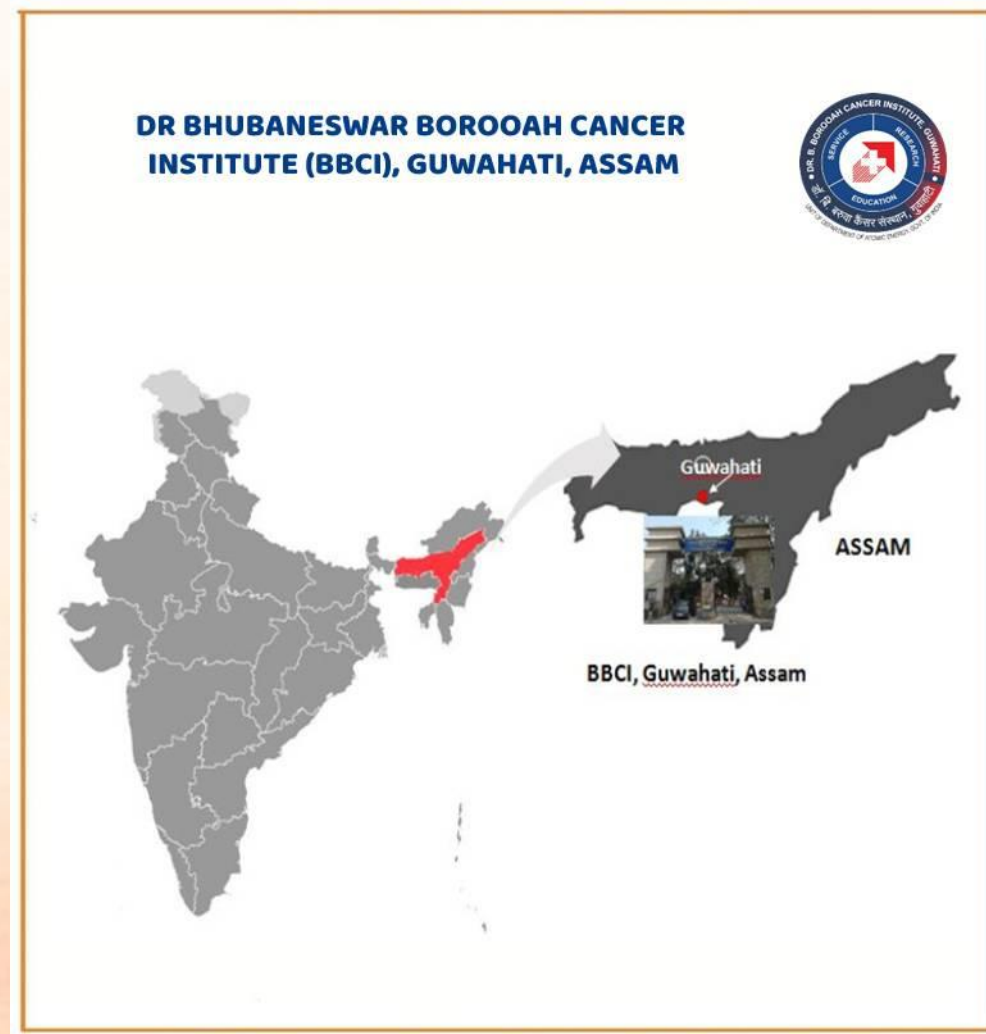
Key Capabilities/Strength

- BBCI has Population Based Cancer Registry (Kamrup Urban Since 2003) and Hospital Based Cancer Registry (BBCI, Guwahati Since 2010) under National Cancer Registry Programme of Indian Council of Medical Research.
- Site comprises of comprehensive cancer surgery and therapy with state-of-the-art equipment and instruments. Department of Radiotherapy, Radio diagnosis and Nuclear Medicine & Molecular Imaging work together on oncology projects.
- Well-equipped Pathology laboratory with facilities for frozen section, immunohistochemistry, immune diagnostic system and blood bank with component separation.
- IEC registered with both CDSCO & DHR.

Registry:

1. Hospital Based cancer registry (HBCR) for all sites.
 2. Population based cancer registry (PBCR) for all sites.
 3. Pattern of care and survival studies for Head & Neck, Breast and uterine cervical cancer.
- Completed 2 Oncology trials.

Geographical Location / Catchment Area



Name of the Site: Homi Bhabha Cancer Hospital (HBCH), Varanasi, Uttar Pradesh

PI: Dr Satyajit Pradhan/ 9415228261/satyajit.pr@gmail.com

Background of the Site

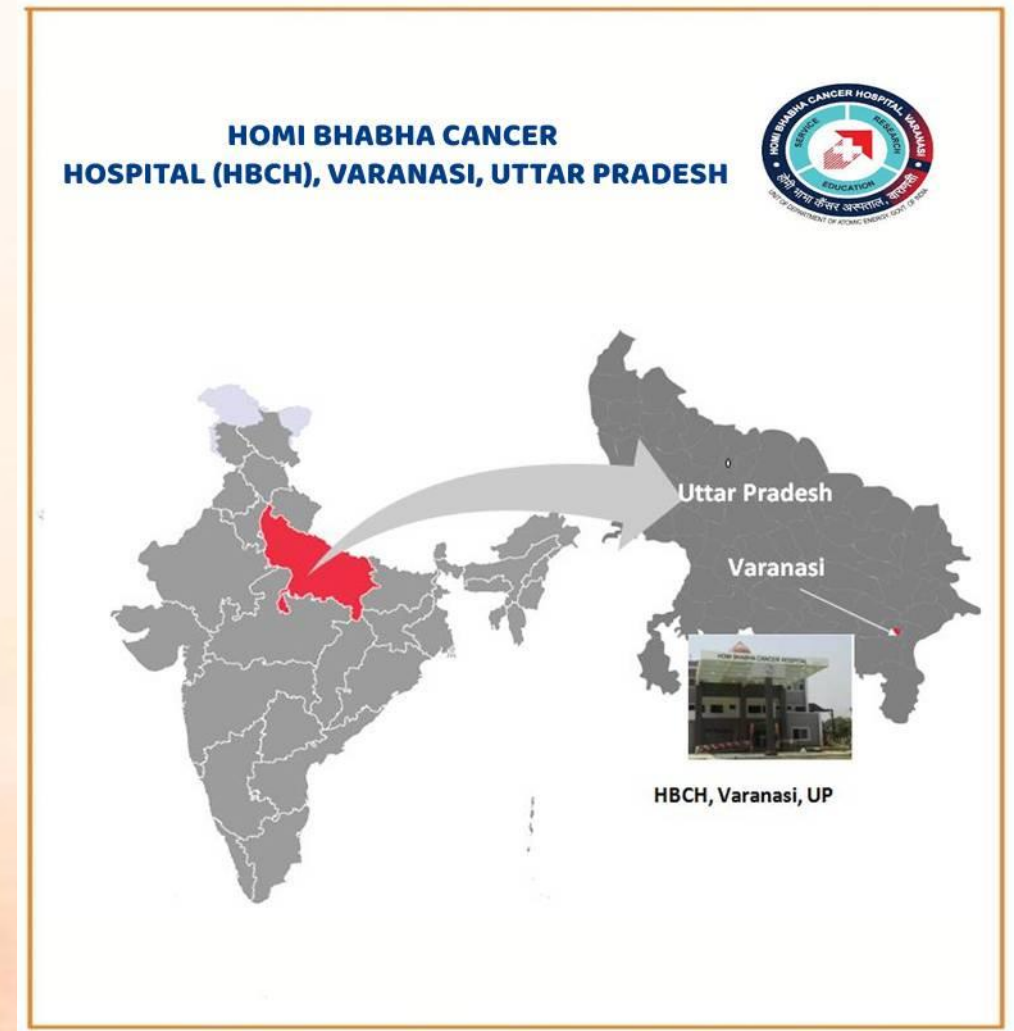
- Homi Bhabha Cancer Hospital, Varanasi is a comprehensive cancer centre for the prevention, treatment and research on Cancer.
- Centre has been providing quality cancer care to the Northern Eastern Railway employees, their dependents and the people of the state with special focus on childhood cancers and adult liquid malignancies including Bone Marrow Transplant facility.
- Comprehensive care provided at HBCH spans from prevention and early detection through diagnosis and treatment to palliative care. The best of experts and equipment have been made available. Integrated multidisciplinary and patient centric approach is adopted for achieving best outcomes.
- A unit of Tata Memorial Centre, Mumbai with 180 beds.
- Aimed to bring comprehensive and high-quality cancer care at affordable costs to the doorsteps of patients of Varanasi and its neighbouring areas and the States of India.
- 13,365 new patients are registered from all over the India and out of which 70% are from Eastern U.P and adjoining areas.
- State of the art infrastructure and laboratories.
- Pioneered several practices changing clinical trials prevention and treatment of cancer.

Key Capabilities/Strength

- Large pool of patients.
- Well experienced and GCP trained manpower including Project Manager, Clinical Research Coordinator and Biostatistician for conduct of multicentric and investigator initiated clinical trials.
- In house Laboratories (NABL Accreditation is in the Process)
- Use of Electronic Medical Record.

- Support of Clinical Research Secretariat with Central Pharmacy and Workstations.
- Institutional Ethics Committee registered with CDSCO and DHR.
- Well established and running Population based Cancer Registry which covers the cancer incidence and mortality in Varanasi District, Uttar Pradesh State, India.
- Total 21 oncology trial completed and 45 oncology clinical trials are ongoing at HBCH, Varanasi.

Geographical Location / Catchment Area



Name of the Site: Cancer Institute (WIA), Chennai, Tamil Nadu
PI: Dr. Selvaluxmy G/ 9841637677/director@cancerinstitutewia.org

Background of the Site

- The Cancer Institute (WIA) established in 1954, also known as the Adyar Cancer Institute, is a cancer treatment and research centre based in Chennai, Tamil Nadu.
- Not-for-profit tertiary cancer centre- one of the largest and oldest in the country
- NABH accredited 671 bedded State Cancer Institute and Regional Cancer Centre for Tamil Nadu.
- State-of-the-art infrastructure for the diagnosis and treatment of cancers.
- Dept. of Molecular Oncology has been designated as Centre of Excellence by Dept. of Science and Technology, Government of India.

Key Capabilities/Strength

- Experienced and trained research team in running pharma and investigator initiated clinical trials.
- GCP trained staff to take up both regulatory and academic trials. The clinical trials team currently manages an evolving portfolio of approximately 25 clinical trials.
- CDSCO and DHR Registered IEC (NABH accredited) established to handle sponsored clinical trials
- Well established Tumor registry- both hospital-based (est.1954) and population-based Madras Metropolitan Tumor Registry (est.1981).
- Running the Tamil Nadu State Cancer Registry- the only state registry in the country covering a population of 80 million (est. 2012).
- Vast experience in community/ preventive oncology- runs community-based screening programs.
- 15 Oncology trials completed.

Geographical Location / Catchment Area

Located in Chennai, Tamil Nadu. Catchment area includes Tamil Nadu, south Andhra Pradesh, Kerala and Karnataka. Also attracts patients from West Bengal and the North-east.



Name of the Site- Malabar Cancer Centre, Thalassery, Kerala
PI: Dr Satheesan B/+91 9895848300/directormcctly@gmail.com

Background of the Site

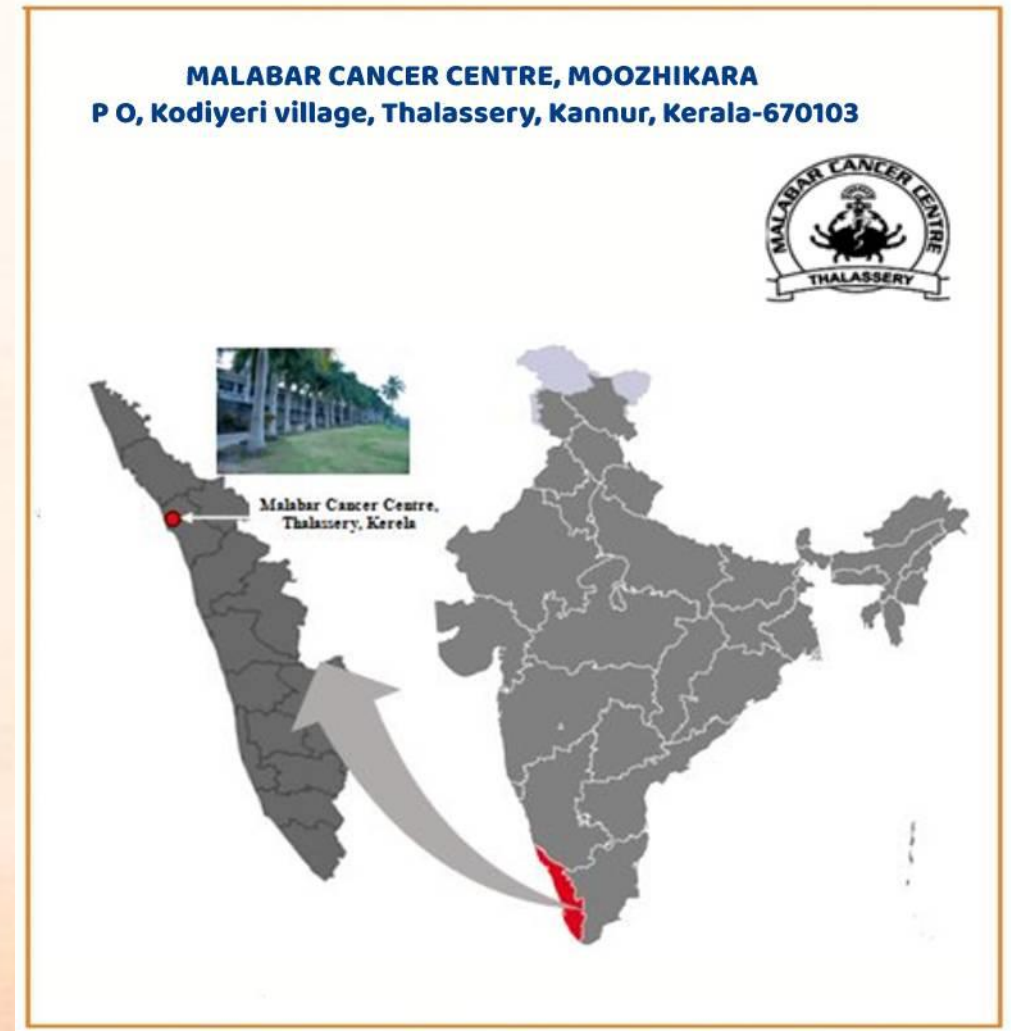
- Malabar Cancer Centre (MCC), is an autonomous institution under the Department of Health and Family Welfare, Government of Kerala.
- Located in the outskirts of Thalassery town in Kannur district in Northern Kerala.
- NABH accredited 200+bed facilities and comprehensive cancer centre in Northern Kerala, One of the three Apex Cancer Centres in the state.
- Yearly around 6000-7000 registrations of newly diagnosed cancer patients and 70,000-80,000 follow up visits.
- State-of-the-art infrastructure for diagnosis and treatment of cancers.
- The Institution is being developed as Postgraduate Institute of Oncology Sciences and Research with equal thrust on Clinical Care, Education and Research.

Key Capabilities/Strength

- NABH accredited and DSIR–SIRO registered hospital.
- Hospital has major diagnostic and treatment facilities for a comprehensive cancer centre.
- Institutional Ethics Committee registered under CDSCO and DHR and Institutional bio safety Committee registered under DBT.
- Dedicated and established Division of Clinical research and Biostatics under Director for clinical research coordination and management.
- Scientific Advisory Committee and Research Advisory Committee- external committees to support the institution.
- Experienced and trained research team in running pharma and investigator initiated clinical trials.
- Ongoing registries are Population Based Cancer Registry (PBCR), Hospital Based Cancer Registry (HBCR), Patterns of care & survival studies in Breast, Cervix & Head & Neck Cancers, Implementation of NCDIR electronic mortality software
- (NCDIR-e-Mor)-strengthen medical certification of cause of death and AML, ALL, APML, CML, Lymphoma under Haematology Cancer Consortium
- Site has two ongoing oncology clinical trials.

Geographical Location / Catchment Area

Malabar Cancer Centre, Moozhikara P O, Kodyeri village, Thalassery, Kannur, Kerala-670103



Name of the Site: Max Super Speciality Hospital, Saket, New Delhi
PI: Dr Ramanadeep Singh/8375017305/ childhoodcancer@gmail.com

Background of the Site

- Max Super Speciality Hospital, Saket (A Unit of Devki Devi Foundation) was established in 2001. Max Institute of Cancer Care (MICC), Saket operational since 2009 and offers a holistic integrated care by consolidating views of experts in surgical oncology, radiation oncology, and medical oncology.
- MICC Saket has 26 oncologists, over 100 beds, 25 day care chairs and 4 Operation Theatres.
- Hospital has 5 full time clinical research professionals to plan and execute clinical trials. In addition, we also have 3 more professionals who support in National Cancer Registry Program (NCRP) at site.
- The Office of Research (OOR) team manages Clinical trials, Investigators led studies and NCRP at Max Healthcare & promotes supports and guides diverse research enterprise. It also acts as a “front door” for new research partnerships. Strong research capabilities and an academic environment have been a priority for Max Healthcare. Since its inception in 2005, the OOR has had a simple and constant mission: To increase the quantity and efficiency of translating fundamental science advances into improved clinical care of our patients.
- Participated in National cancer registry programme (NCRP) funded by ICMR in 2013.

Key Capabilities/Strength

- Experienced team with PI has conducted 4 regulated Clinical Trials in past and currently conducting 3 more regulated clinical trials and has total 5 Trial related publications in high index journals.
- Site has detailed SOPs (Standard Operating Procedures) for Clinical Operation and Ethics Committee.
- A scientific committee and CDSCO registered Independent Ethics Committee. The ethics committee meets at least once a month and reviews clinical trials which may be sponsored or investigator led.

The patient records are saved and maintained in Paper and Electronic formats. Max maintains electronic patient records in access-controlled systems i.e., HIS, CPRS and E prescription.

Geographical Location / Catchment Area



Name of the Site: North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences (NEIGRIHMS), Shillong, Meghalaya
PI: Dr. Caleb Harris/+91 9969375606/calebhar@outlook.com

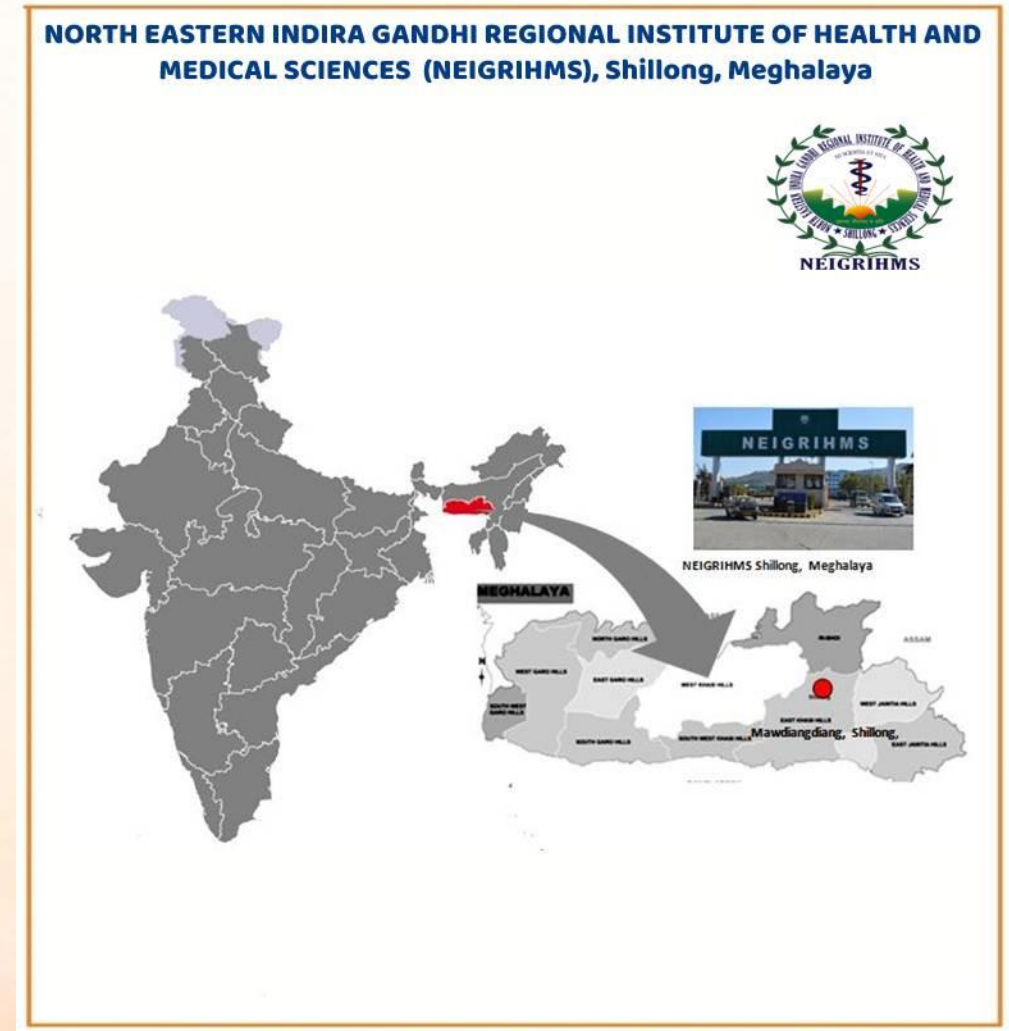
Background of the Site

- NEIGRIHMS is a medical institute established by Government of India in 1987, being registered as an Autonomous Central Government Institution.
- Department of Surgical Oncology and Radiotherapy are functional.
- Multidisciplinary Approach, with regular meetings for all patient decisions.
- Existing Hospital Based Cancer Registry (NCDIR).
- NEIGRIHMS hosts the Regional Centre for telemedicine.
- Involved in multiple multi-centric projects.
- Over 1490 new cancer patients and 6991 follow up patients were seen in 2019-2020.

Key Capabilities/Strength

- Evidence-based multidisciplinary approach to patient care.
- Strong radiology back up with excellent interventional radiology support.
- Dedicated pathology team.
- Most of the supra-major and major surgeries for cancer are being performed routinely.
- Part of Gall bladder cancer Registry (NCG multi-centric study)
- In-house Scientific and Ethics Review Committee (CDSCO and DHR registered).
- Two multi-centric Randomized Controlled Trials on-going.

Geographical Location / Catchment Area



Name of the Site: Regional Cancer Centre(RCC), Thiruvananthapuram, Kerala

PI: Name: Dr Beela Sarah Mathew/+91 9846520565/beela@rcctvm.gov.in

Background of the Site

- The Regional Cancer Centre, Thiruvananthapuram is a grant-in-aid comprehensive cancer centre, set up in 1981 under the Government of Kerala.
- NABH accredited facility with state-of-the-art diagnostic and treatment facilities for management of cancer.
- Over 16,000 new cancer patients and 2,00,000 review patients are seen annually.
- RCC is under the network of the National Cancer Registry Programme and maintains a Hospital Based Cancer Registry and Population Based Cancer Registry covering the districts of Thiruvananthapuram, Kollam, Alappuzha & Pathanamthitta (9.3 million population).
- Hospital has a Basic Cancer Research division.
- Site-specific multi-disciplinary team for clinical services.

Key Capabilities/Strength

- Experienced Faculty in conducting GCP compliant trials. Trained Clinical Trial Co-ordinators and Research Nurses and other staff.
- In-house Scientific and Ethics Review Committee (CDSCO and DHR registered).
- Space and infrastructure available for trial requirements including patient counselling, storage of investigational product, biological samples and trial records, monitoring.
- Established Bio-statistics division for data analysis.
- RCC has been conducting clinical trials since 1995. Oncology clinical trials completed- 169; ongoing-16.

Geographical Location / Catchment Area



Name of the Site: Christian Medical College (CMC), Vellore, Tamil Nadu

PI: Dr. Vikram Mathews/+91- 94433-39340/ vikram@cmcvellore.ac.in

Background of the Site

- Christian Medical College, Vellore is a private, Christian community-run medical school, hospital and research institute, established in 1900. The Institute includes a network of primary, secondary and tertiary care hospitals in and around Vellore, Tamil Nadu, India.
- Department of Haematology, CMC, Vellore delivers clinical trials with high biomedical research into the following disease areas: aplastic anaemia (AA), myelodysplastic syndromes (MDS), acute myeloid leukaemia (AML), chronic myeloid leukaemia (CML), multiple myeloma (MM), lymphoma, chronic lymphocytic leukaemia (CLL) and haematopoietic stem cell transplantation (HSCT).
- Department manages a large diverse portfolio of research activity, which includes commercial and non-commercial research, phase I to phase IV studies, DBT trials and Investigator initiated studies for the past 20 years.

Key Capabilities/Strength

- Experienced team of Investigators / Co-Investigators / Support team who can carry out the clinical trial studies in compliance with the local / International regulatory guidelines and Good Clinical Practices. Team consists of GCP trained - 1 Project manager, 5 clinical research coordinators, 2 Study Nurses, 2 Data entry operators overseeing clinical trials in the department.
- Site is well versed in managing Phase-I to Phase-IV clinical trials with all haematological systemic disorders.
- IEC is registered with CDSCO.
- In house NABL accredited lab for clinical investigations.
- 24hr patient care for patient's clinical management with multi-specialty support available at the Institution.
- Capability of writing up various Investigator initiated research including in-house design of protocols, case record forms, Informed consent forms, patient information sheet, design of source templates, national regulatory submissions, follow of patients for chronic conditions and implementation of retention strategies for long term data collection.

- National and International registry collaborative work with multi-sites and as a collaborating centre for various Investigator initiated research protocols.
- CMC, Vellore is currently involved and maintains the Prospective registries such as Hematological Cancer Consortium: Hematological Cancers Registry for Acute Lymphoblastic Leukemia (ALL), Chronic Myeloid Leukemia (CML), Acute Myeloid Leukemia (AML), Acute Promyelocytic Leukemia (APML) and Lymphoma Registry.
- Clinical trials team currently manages an evolving clinical trials portfolio of approximately 50 studies.

Geographical Location / Catchment Area

Vellore is a city in the state of Tamil Nadu, in southern India



Name of the Site: Cachar Cancer Hospital & Research Centre (CCHRC), Silchar, Assam

PI: Name: Dr. Ravi Kannan/+91- 9854040424/
ravi.kannan@cacharcancerhospital.org

Background of the Site

- Established in 1996, Cachar Cancer Hospital and Research Centre (CCHRC), is located in the outskirts of Silchar town in the Barak Valley of Assam in India. It is administered by the Cachar Cancer Hospital Society, a non-profit NGO.
- Society came into existence in 1992 as a result of a desperately felt need for a cancer hospital since the only cancer hospital in the entire north east was in Guwahati.
- The three principal objectives of CCHRC are: (1) to make people aware of cancer, adopt preventive measures and seek early detection (2) to establish a full-fledged cancer hospital to provide meaningful services to all suffering people and (3) to set up a cancer research centre.
- Over 4000 new patients and over 25000 follow up visits of patients annually.
- All the departments of hospital render 24x7 hours of service to the patients. The important departments like pathology, Radiology, Medical Oncology, Surgical Oncology, Radiation Oncology, Pain and palliative Care, Molecular Oncology, Cancer genetics Clinic, Microbiology, Diet and Nutritional Science, Nursing, Information Technology, Epidemiology and Tumour Registry, Resource management Team, Medical social work team, Preventive Oncology team, and the hospital Pharmacy team works actively and uniformly to deliver quality service to the patients.
- Site is ready to establish a clinical research secretariat (CRS) so as to facilitate nationally and in internationally supported projects.

Key Capabilities/Strength

- CCHRC is the only comprehensive cancer centre in southern Assam
- Hospital has implemented several measures to enable patients to complete treatment successfully without delay and breaks: No cost/ low-cost treatment, Quick diagnostic times, Low-cost pharmacy, Dharamshala (Guesthouse), Phone call follow up, home visits and home-based care, Tele-Medicine centres and Satellite clinics, Resource support.

- Site has an active preventive oncology programme which includes a vigorous anti-tobacco campaign and early cancer detection programme. The costs of conducting awareness/ screening camps are borne by the hospital.
- In house lab facility which runs 24X7 functioning state of the art laboratories with facilities for histopathology, cytology, immuno-histochemistry, clinical pathology and hematology provided diagnostic services.
- IEC registered with CDSCO and DHR.
- The trial Team consists of GCP trained principal Investigator, CO-Investigators, Clinical Trial Coordinators, Data Entry Operator, Research Nurses, and Pharmacist.
- Site has 11 ongoing oncology Clinical Trials (regulatory and academic).

Registries maintained at site:

1. Establishment of Hospital Based Cancer Registry (HBCR) and participation on Atlas and PCSS project of (NCRP)ICMR
2. To set up Population Based Cancer Registry at karimganj and Hailakhandi and Dima Hasao.
3. Hospital Based Cancer Registry and pattern of care and survival studies.
4. Implementation of NCDIR e-Mortality software (NCDIR e-mor) in hospitals of NCRP network in NE India.
5. DHR-ICMR Advanced Medical Oncology Diagnostic Services (DIAMOnDS) project.
6. Part of Gall bladder cancer Registry (NCG multicentric study)
7. Database creation for computational predictive analysis of treatment response assessment in Esophageal cancer patients in India”

Geographical Location / Catchment Area

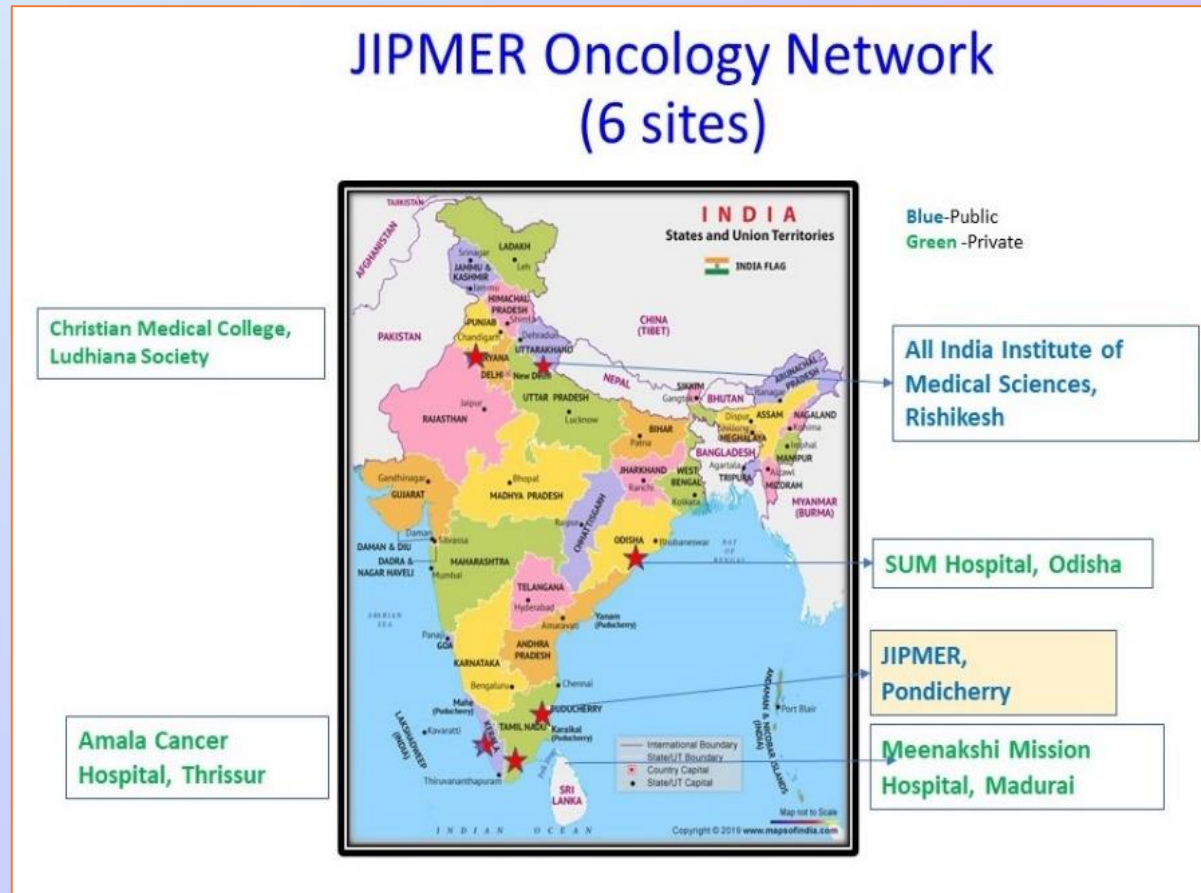
CCHRC serves an extremely impoverished community of patients from Assam (mainly from Cachar, Karimganj, Hailakandhi and Dima Hasao districts), Tripura and the western part of Manipur



Oncology-2

JIPMER (Lead Site)

The aim is to establish Network of Oncology Clinical Trials in India (NOCI), which will enhance the capability for conduct of Industry-sponsored trials of new cancer drugs and biosimilars by: Manpower training and infrastructure development, process harmonization between centres and to conduct collaborative investigator - initiated research. The purpose is to strengthen Clinical Trial capacity and to create a registry of common cancers which gives background data on outcomes. The network brings 6 large oncology centres representing different regions of India (North 2, South 3 & East 1) with access to large patient pool and increase their clinical trial capabilities. Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry is lead site of the network. An individual patient data registry of cancer care and outcomes being developed in collaboration with six other centres across India. A common protocol for establishing the database has been established among all centres and approved by Institutional Ethics Committee. Site started creating database for 06 common cancers (Lung, Head and neck Cervix, Ovary, Breast and Brain cancers) where data of patients are captured to a software aiming to aid in real-world evidence of disease manifestation and treatments.



Name of the Site:

Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry

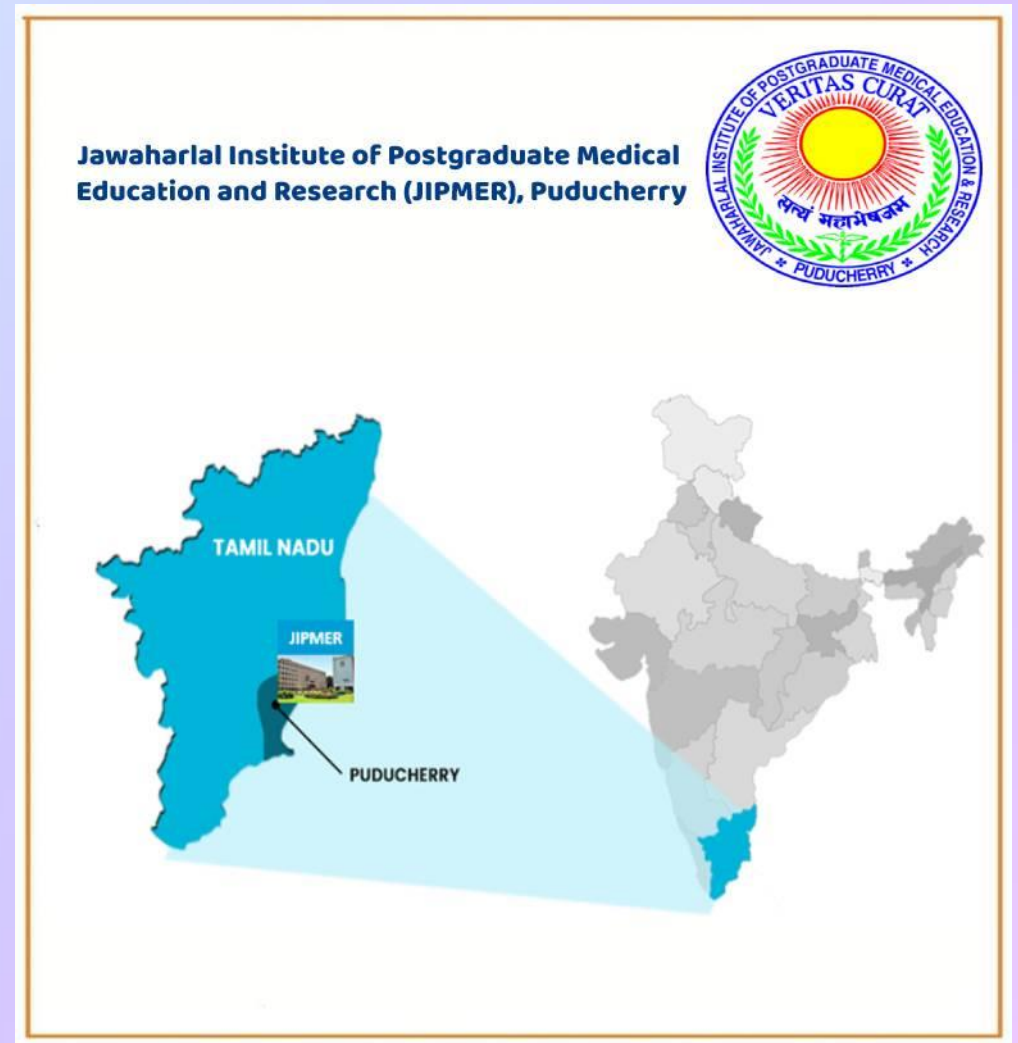
PI: Dr Prasanth Ganesan/+91 9940339189/p.ganesan@jipmer.edu.in

Background of the Site

- JIPMER, established in the 1960s, was designated as an Institution of National Importance in 2008.
- 2000 bedded multispecialty centre serving patients.
- Department of Medical Oncology has a Bone Marrow Transplant unit, and a Clinical Research unit.
- Enrolled several hundred patients in various investigator-initiated and sponsored clinical trials.
- Emerging as an important centre for teaching, and research in oncology.

Key Capabilities/Strength

- Each year, around 5000 new cancers cases are registered and treated at the centre between the departments of medical, radiation, and surgical oncology.
- Experienced in regulatory trials and GCP trained team ready to conduct sponsored clinical trials.
- Institutional Ethics committee (IEC) registered with CDSCO & DHR and DSIR and conduct IEC meetings every month.
- Additional committees at site- Scientific advisory committee & sponsored clinical trial committee
- Multiple National and International Sponsored Clinical trials involving targeted and biosimilar molecules are ongoing in the department. Completed 20 oncology clinical Trial Studies and 09 sponsored clinical trials are ongoing.

Geographical Location / Catchment Area

Name of the Site:

Institute of Medical Sciences (IMS) & SUM Hospital, Bhubaneswar, Odisha

PI: Dr Soumya Surath Panda/ +91 8895370579/ ssp_scb@yahoo.com, dr.ssp82@gmail.com

Background of the Site

- Institute of Medical Sciences & SUM Hospital is the Medical College and hospital of Siksha 'O'Anusandhan University established in the Year 2007.
- 1500 bedded multispecialty NABH Accredited hospital with NABL accredited lab facility serving patients.
- Department of Medical Oncology is operationally active since October 2014.
- Around 3500 new cancers, every year treated at the centre between the departments of medical, radiation, surgical oncology and hematology.
- Only Centre from Eastern India for the development of a multi-centre clinical trial network in oncology.

Key Capabilities/Strength

- Dedicated committee to handle sponsored clinical trials to help review and processing before IEC submission.
- IEC registered with CDSCO.
- In house NABL accredited laboratory.
- Equipped with Electronic Medical Record (EMR) system.
- Trained (ICH- GCP and SOP) Team with experience in multi-centre trials and many years of clinical experience.
- Site has conducted 04 clinical trial in cancer indications such as Metastatic Breast Cancer, Diffuse large B-cell lymphoma, Multiple Myeloma & Pancreatic Cancer. One ongoing Phase III clinical trial for breast cancer.
- Enrolled many patients in various investigator-initiated and sponsored clinical trials including COVID vaccine COVAXIN & COVOVAX trial.

Geographical Location / Catchment Area

Name of the Site:

All India Institute of Medical Science(AIIMS), Rishikesh, Uttarakhand

PI: Name : Dr. Amit Sehrawat/ +91 99584

74477/dramitsehrawat@gmail.com, amit.monc@aiimsrishikesh.edu.in

Background of the Site

- AIIMS Rishikesh, an Autonomous Institute of National Importance was established in 2012.
- 1000 bedded multispecialty tertiary care centre serving patients in the region.
- Department of Medical Oncology Haematology started its services in the year 2017.
- Medical Oncology Haematology Department along with the Department of Pharmacology runs a Clinical Trial Unit.
- More than 10000 cancers patient's admissions and OPD consultations are done every year in the Oncology Services AIIMS Rishikesh (Departments of Medical, Radiation, and Surgical oncology).

Key Capabilities/Strength

- 24x7 Trauma lab is NABL accredited
- CDSCO and DHR Registered Institute IEC established to handle sponsored clinical trials. Research Review Board committee established to help review and processing before IEC submission.
- Two regulatory Oncology Drug Trials are being Conducted in the Department of Medical Oncology Haematology.
- Clinical Operations Team handles sponsored Clinical Trials with GCP trained Staff.

Geographical Location / Catchment Area

Name of the Site: Christian Medical College & Hospital (CMCL), Ludhiana, Punjab

PI: Dr. Ashwin Oommen Philips/+91 90036-

35373/ashwin.philips@cmcludhiana.in, drashphilsmog@gmail.com

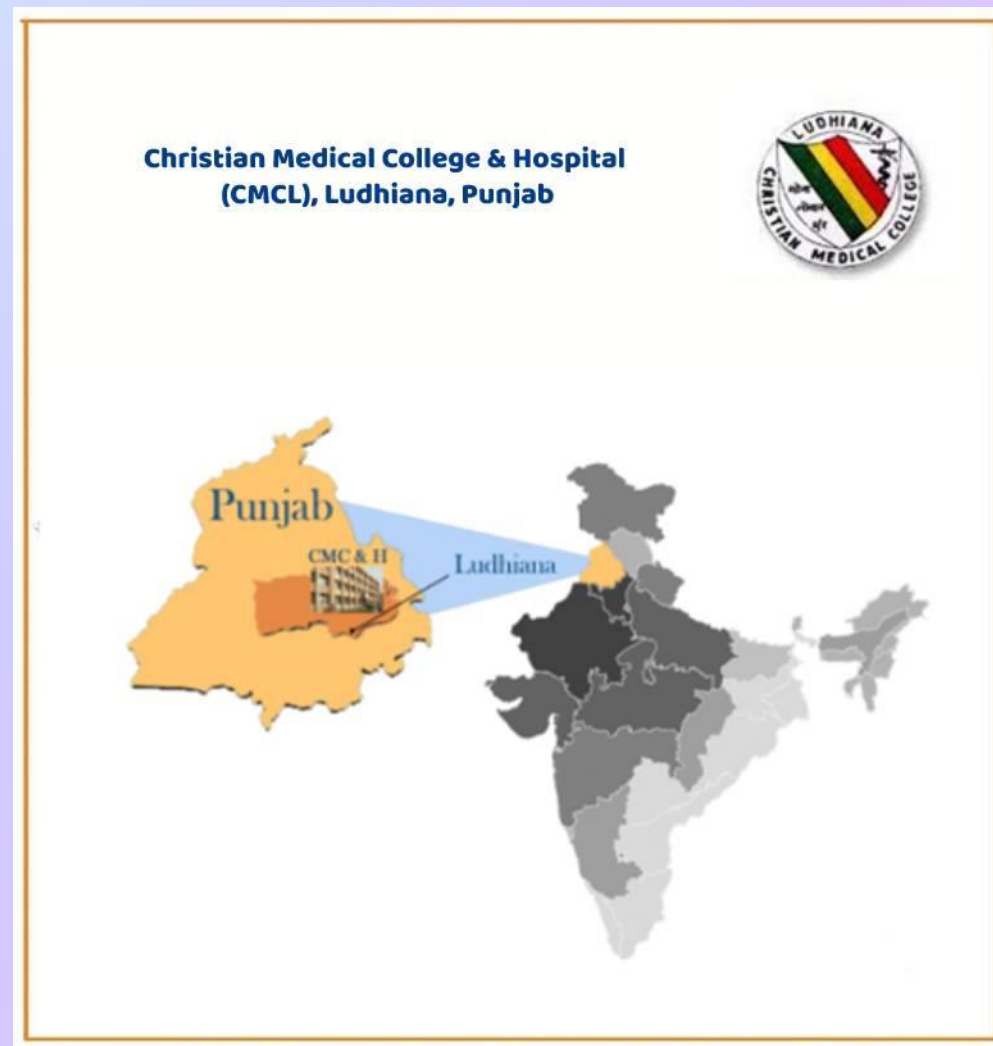
Background of the Site

- The Christian Medical College and Hospital is a private, minority-run teaching hospital in Ludhiana, India.
- Founded in 1894, it was then the first medical school for women in Asia.
- It recently celebrated 125 years of its distinguished service to the nation and to the entire world.
- Christian Medical College & Hospital, Ludhiana, (CMCL), is one of the first institutions in North India, to offer comprehensive treatment to Cancer patients
- The Department of Medical Oncology serves as a centre for diagnosis and multidisciplinary evidence-based treatment for all solid malignancies such as Breast Cancer, NSCLC/SCLC, Gastrointestinal/Genitourinary malignancies, Squamous cell carcinomas and other metastatic malignancies.

Key Capabilities/Strength

- Institutional Ethics Committee has been registered with CDSCO & DHR, and conduct IEC meetings every month
- Microbiology Lab is NABL Accredited
- Pharmacological services- Patient Counselling related to disease and therapy with referenced information material, Medication therapy management
- Patient Registries are being developed are for Breast, Ovary, Cervix, Brain and Head & Neck
- Medical Oncology Team handles sponsored Clinical Trials with GCP trained Team.
- Two ongoing oncology clinical trials at the site.

Geographical Location / Catchment Area



Name of the Site: Meenakshi Mission Hospital & Research Centre(MMHRC),Madurai, Tamil Nadu
PI: Dr Krishnakumar Rathnam/+919380417299/ kkrathnam@gmail.com

Background of the Site

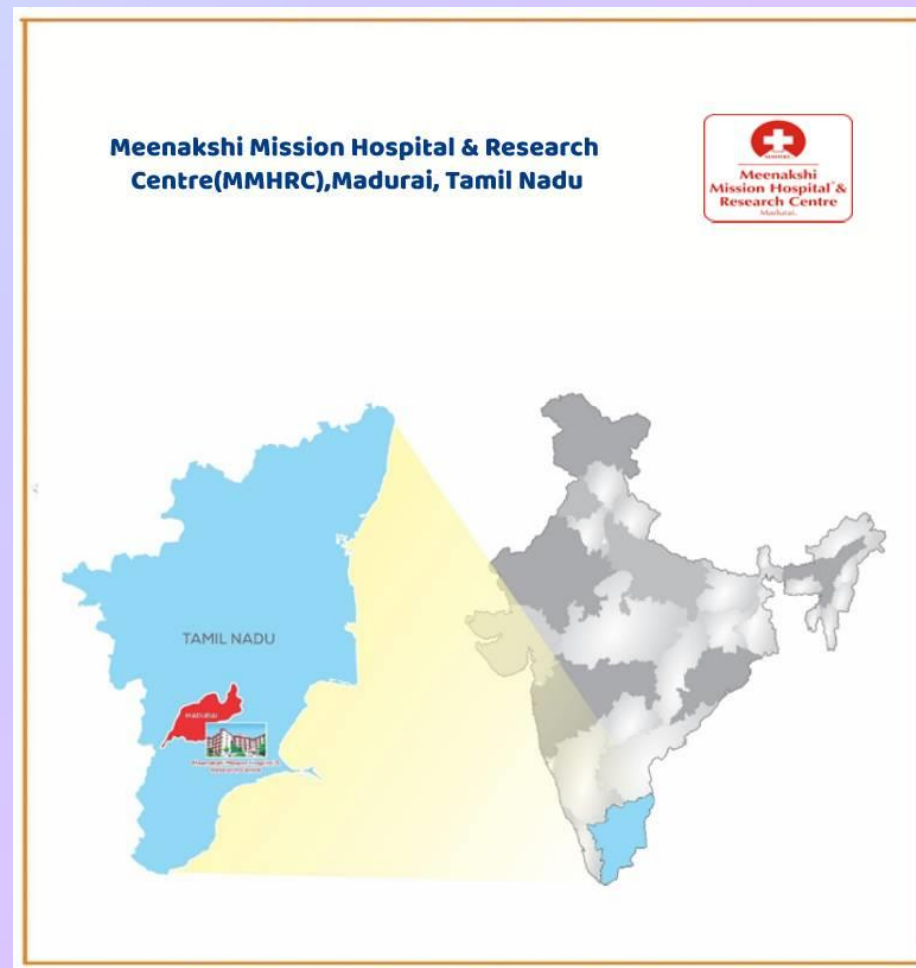
- MMHRC established in 1985, caters to patients from different socio-economic strata from a geographical radius of 300 km in the state of Tamil Nadu.
- NABH accredited, 24 x 7 functioning emergency department and well equipped round the clock intensive units.
- Institution has integrated medical services from other speciality departments like Surgery, Cardiology, Nephrology and Critical Care medicine.
- Supported by in house radiology department with integrated nuclear medicine and PET scan services.
- Site is already a member of the “National Cancer Grid” and follows cancer specific guidelines uniformly practiced around India.

Key Capabilities/Strength

- MMHRC has been conducting clinical trials since 2008 and the site has been successfully audited by Global regulatory agencies like FDA: 4 times and DCGI: 01time till date.
- As one of the most experienced sites in clinical research, completed 70 oncology clinical Trial Studies and 14 Ongoing studies including 4 oncology clinical trials.
- The Principal Investigator has experience as in over 60 trials as a principal/Co investigator till date.
- Clinical trial department is well equipped with manpower and the entire workforce works as a single team.
- Separate department for clinical research with restricted access, sufficient man power with proper training in GCP and New clinical trial rules 2019, with enough experience and proper backup.
- Working with 10 clinical research Coordinators and one project manager reporting to Head of the Department of Clinical Research.
- Well-equipped to conduct phase 1 to 4 clinical trials, in house NABL accredited laboratory.

- Conducted clinical trial in almost all the indications in cancers (Metastatic Breast Cancer, NSCLC, NHL, mCRC, Early Breast Cancer, DLBCL, Multiple Myeloma, Head & Neck, Cervical cancer, Prostate, pancreatic Cancer, Renal cell carcinoma, endometrial cancer, Mantle cell lymphoma, Ovarian cancer, CML, AML, GBM and advanced refractory solid tumors.
- Institutional ethics committee is CDSCO & DHR registered and meets every month and in an expedited manner in case of necessity.

Geographical Location / Catchment Area



Name of the Site:

Amala Cancer Research Centre, Thrissur, Kerala

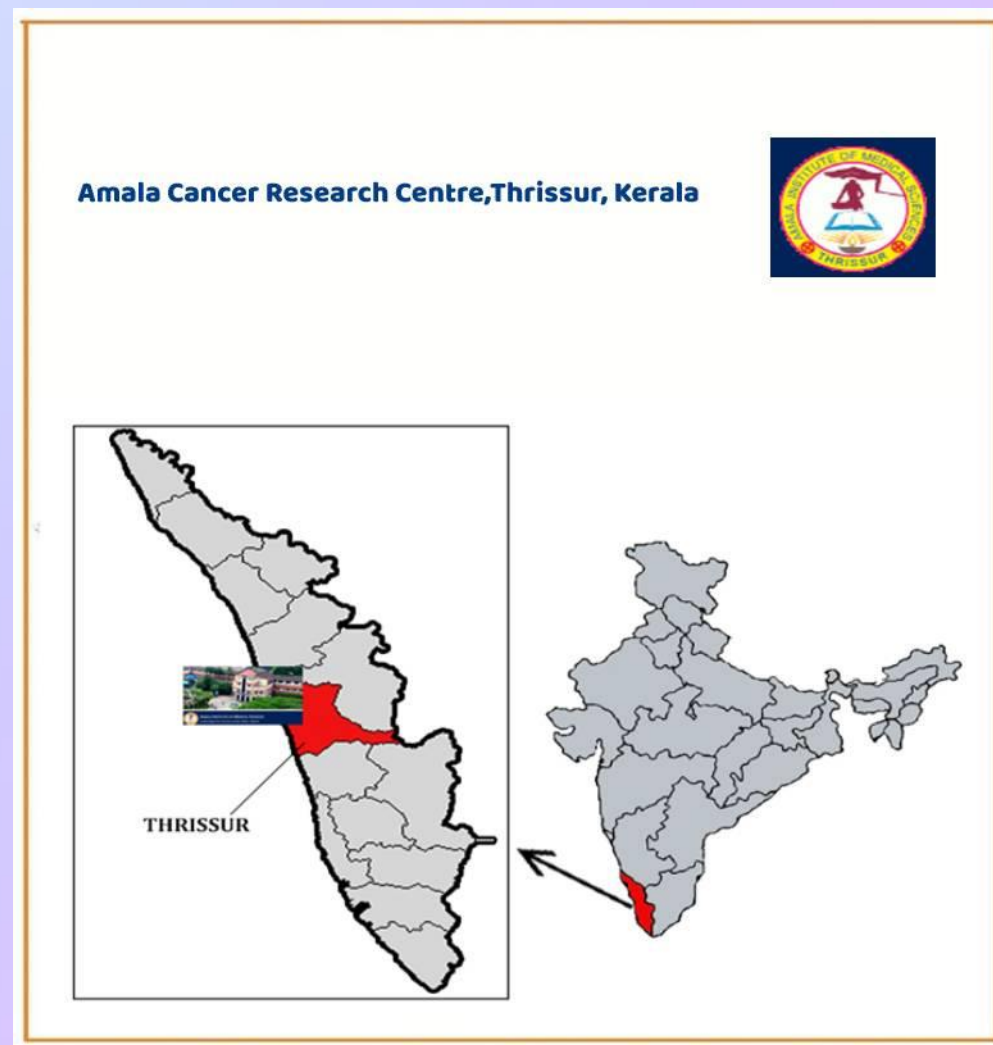
PI: Dr Sunu Cyriac/+91 9567602426/drsunucyriac@gmail.com

Background of the Site

- Amala Institute of Medical Centre Thrissur established in 1978, was the first stand-alone cancer centre in Kerala.
- Site is well established and holds prestigious accreditations like NABH, and ISO certifications and is currently a 1100 bedded medical college with all modern cancer care facilities.
- A most sought-after medical college of the state of Kerala, in a sprawling 42 acres campus.
- A separate Cancer Research facility (Amala Cancer Research Centre) in campus focused on basic cancer research.

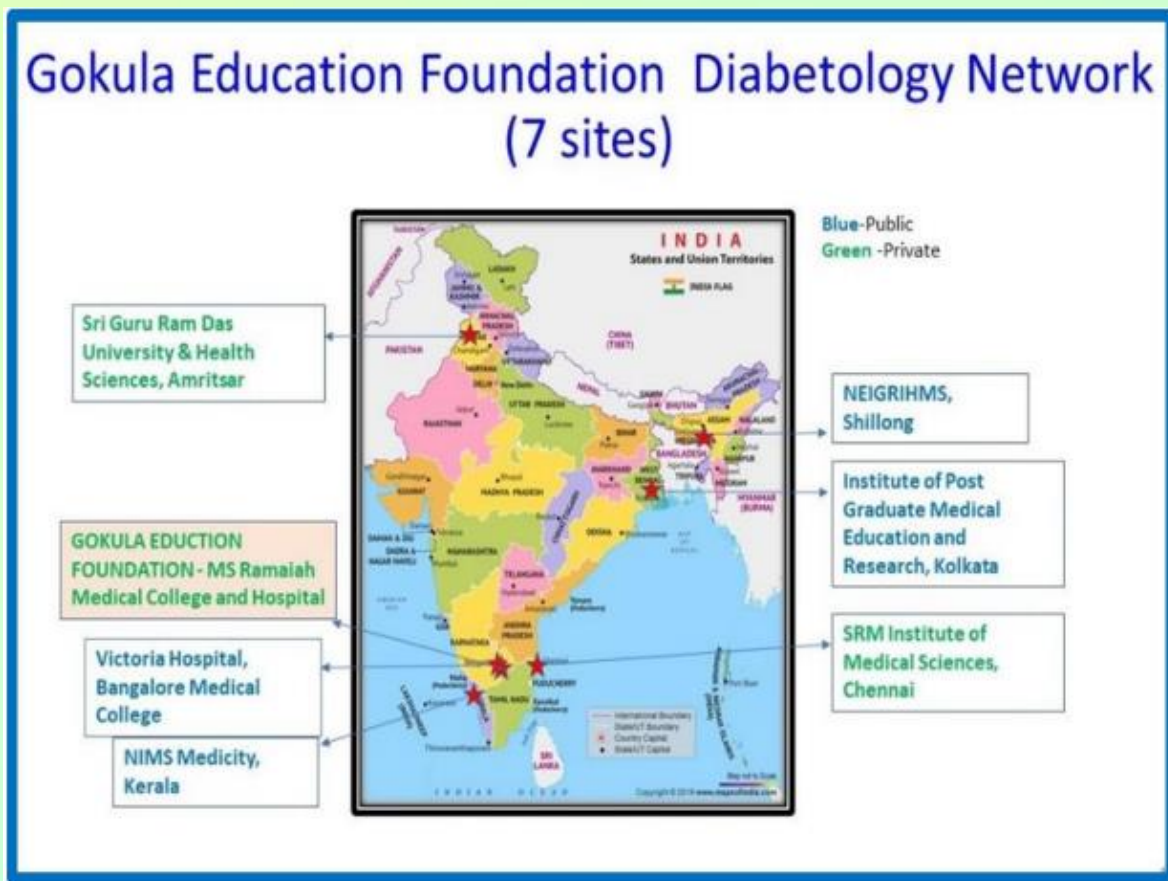
Key Capabilities/Strength

- Around 3000 new cancer patients per year at the centre between the departments of medical, radiation, and surgical oncology.
- The Department of Medical Oncology and Haematology was established in early 2000 have 4 full time faculties trained from the most prestigious cancer centres of India and abroad.
- There is a dedicated basic cancer research wing in campus aiding in more collaborative research.
- Dedicated committee to oversee sponsored clinical trials to help review and processing of trials apart from scientific committee and Ethics board. IEC is registered with CDSCO.
- Site has qualified, experienced and GCP trained researcher group to undertake clinical trial in oncology.
- Additional supports from all allied departments as well as in-house biostatistics department present.
- Have a most advanced full-fledged lab and MOU with multiple NABL accredited clinical laboratories

Geographical Location / Catchment Area

Diabetology

To establish pan Indian network of clinical trial sites with expertise in handling diabetes trials and to ensure uniformity in training, SOPs, access to technology, regulatory & GCP compliance in network collaboration. The aim is to make all the network centers world class stature in terms of research and training. To ensure representation of all geographical parts of the country, the sites are chosen in such a way that there is a right blend of experienced and inexperienced sites, as well as representation of both government and private organizations. 4 Public hospitals (Victoria Hospital, Bangalore Medical College & Research Institute, Bengaluru, North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences, Shillong, NIMS Medicity, Aralumoodu & Institute of Post Graduate Medical Education and Research SSKM hospital, Kolkata) and 3 private centers (Sri Guru Ram Das University of Health Sciences, Amritsar, SRM Institutes for Medical Science, Chennai & M.S. Ramaiah Medical College and Hospitals, Bangalore) are part of Diabetology network. The lead site of the Diabetology network is M.S. Ramaiah Medical College and Hospitals, Bangalore. Through this initiative the plan is to strengthen Clinical trial capacity across different sites of the CTN and to develop registry of diabetic population available for Clinical Trials. The site is creating Type 1 & Type 2 Diabetes Mellitus Registry in which patient data is collected from 7 centers in the network across India. A common IT platform for collecting Registry database has been developed, the database can be used to get the pool of eligible patients for future clinical trials in Diabetology.



Name of the Site: Gokula Education Foundation (GEF), M.S.Ramaiah Medical College and Hospitals. Bangalore, Karnataka
PI name: Dr. Mala Dharmalingam/+91- 9845208163/
drmaladharmalingam@gmail.com

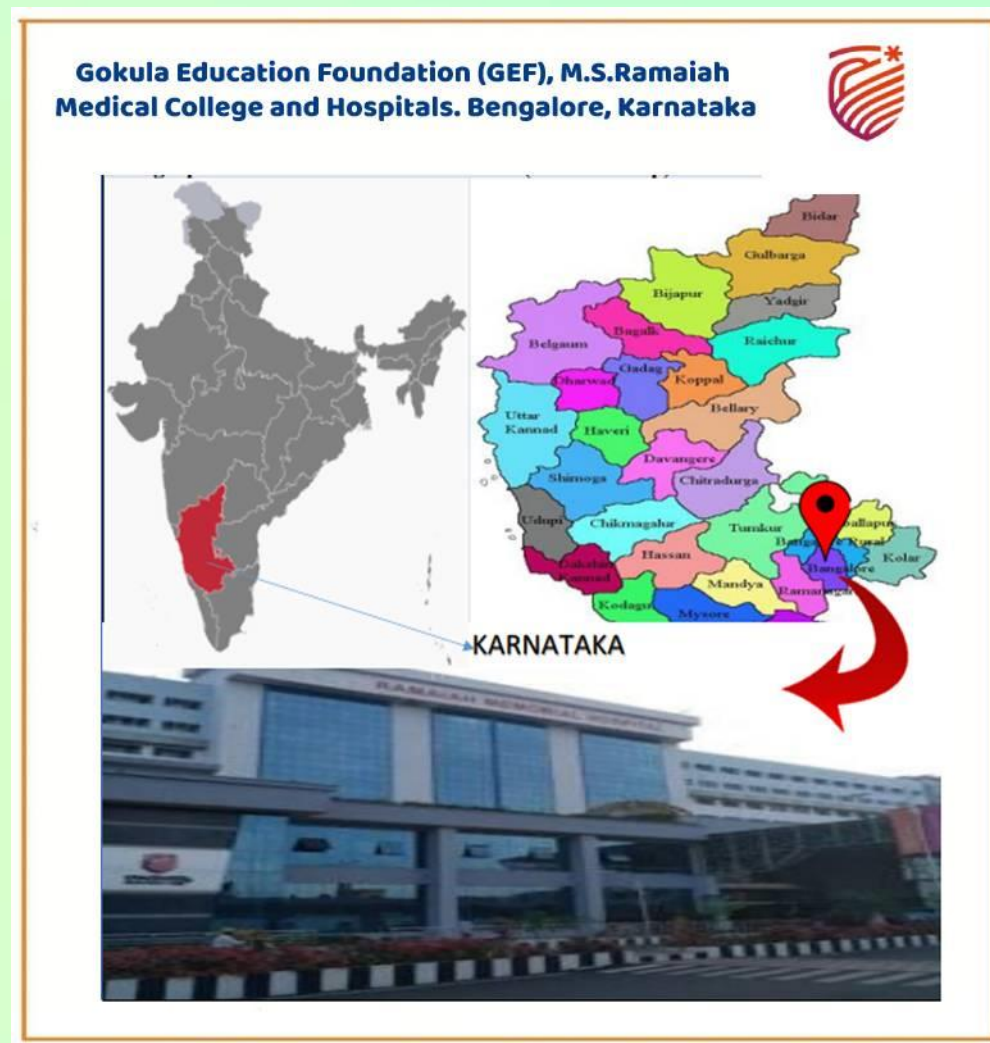
Background of the Site

- MS Ramaiah Hospital is one of the largest private hospital in north Bangalore located in sprawling 75 acres campus.
- The Ramaiah Medical College was established in 1979. The hospital was set up in the campus in 1984- provides tertiary care.
- Hospital is 1331 bedded having all super specialty services, with recent infrastructure for handling emergencies and providing good care to patient.
- Clinical Research Centre has a large team of well trained, experienced, qualified Study coordinators & 5000 Sq. Feet of dedicated area for clinical research.

Key Capabilities/Strength

- Experienced & GCP trained team- PI, Co-I, Project Manager, Medical Officers, CRCs, Quality & Training Managers, Biostatistician and Data Entry Operator.
- NABH accredited Institution Ethics Committee registered with DCGI and DHR.
- Equipped with NABL accredited clinical investigation lab
- Carried out patient registries in Type 1 diabetic, pituitary adenoma, hyper parathyroid and DVT.
- Conducted more than 250 clinical trials and more than 60 trials in Diabetic population for Indian as well as international pharmaceutical companies. Research is conducted under strict regulatory and GCP guidelines.
- Site has faced USFDA audit in 2007 with no form 486 being issued. Site has been audited by DCGI in 2011 followed by many surprise DCGI inspections and also by the Malaysian Regulatory Agency in 2017 with no major findings.

Geographical Location / Catchment Area



Name of the Site :Victoria Hospital, Bangalore Medical College and Research Institute (BMCRI), Bangalore, Karnataka

- **PI name: Dr. K.R. Raveendra/+91 9448134587/9844252189/
drkraveendra@gmail.com, harryraykar@yahoo.com**

Background of the Site

- BMCRI established in 1900 located in heart of the city in a sprawling 200 acres campus.
- The site is Government Medical college and regional tertiary care Hospital.
- Attract 1000+ walk in patients per day.
- Super specialty facility with nominal cost services.
- 2000+ beds of occupancy with 100+ ICU beds

Key Capabilities/Strength

- Enough space with well establish clinical research area and quality infrastructure.
- Equipped with NABL accredited clinical investigation lab and CDSCO registered IEC.
- Dedicated and GCP trained site team including PI, Co-I, CRCs etc. to undertake clinical trial.
- Successfully delivered 100+ Global Studies. Faced US FDA with Zero 483.
- Completed more than 50 Global and Indian trials in Diabetology and 01 is ongoing

Geographical Location / Catchment Area



Name of the Site: Noorul Islam Institute of Medical Sciences (NIMS Medicity), Trivandrum, Kerala
PI: Dr. Sreejith N Kumar/+91- 9847204360/sreejithnkumar@gmail.com

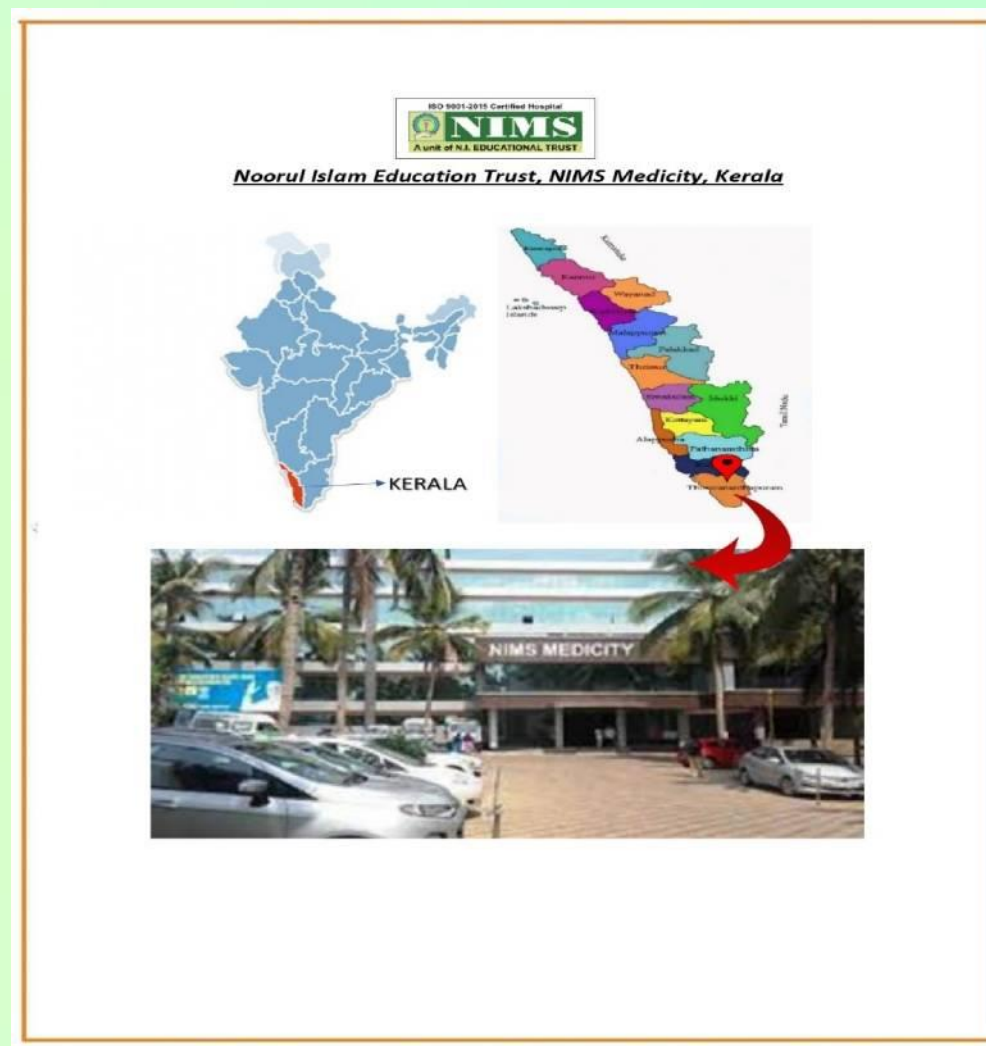
Background of the Site

- NIMS Medicity, part of the 61year old Noorul Islam Educational Trust, is a 350 bedded tertiary care Super Specialty Hospital, established in the year 2005.
- One of the largest health care centres in South Kerala and South Tamil Nadu.
- Among the specialized hospital and Healthcare Centre in India with more than 200 Super Specialists of high calibre working with State-of-the-art medical gadgets, totally dedicated to complete health restoration along with more than 1500 nursing and paramedical staffs.
- First healthcare Institution in Kerala to install a fibro scan (liver scan machine), and also the first leuko reduction blood bank.
- Asia's first hybrid green energy cardiac catheterization lab was established in NIMS

Key Capabilities/Strength

- NABL accredited and ICMR approved Laboratory inside the hospital with Pathology, Biochemistry, immunochemistry, Haematology, Microbiology, Serology, Molecular Genetics & Molecular biology, COVID testing: RTPCR, True Nat antigen testing and next generation sequencing capabilities.
- Dedicated Clinical Research department with all required infrastructure, experienced Investigators, staffs and separate quality department to oversight all research activities.
- NIMS Institutional Ethics Committee situated inside the hospital is NABH accredited and registered with DHR & CDSCO.
- Site is conducting DCGI approved Clinical Trials since 2013.
- There are 3 completed clinical trials in Diabetology & 01 is in pipeline.

Geographical Location / Catchment Area



Name of the Site: Sri Guru Ram Das University of Health Sciences (SGRDUHS), Amritsar, Punjab
PI : Dr. Gurinder Mohan/ +91 9815341556/drgurinder1968@gmail.com

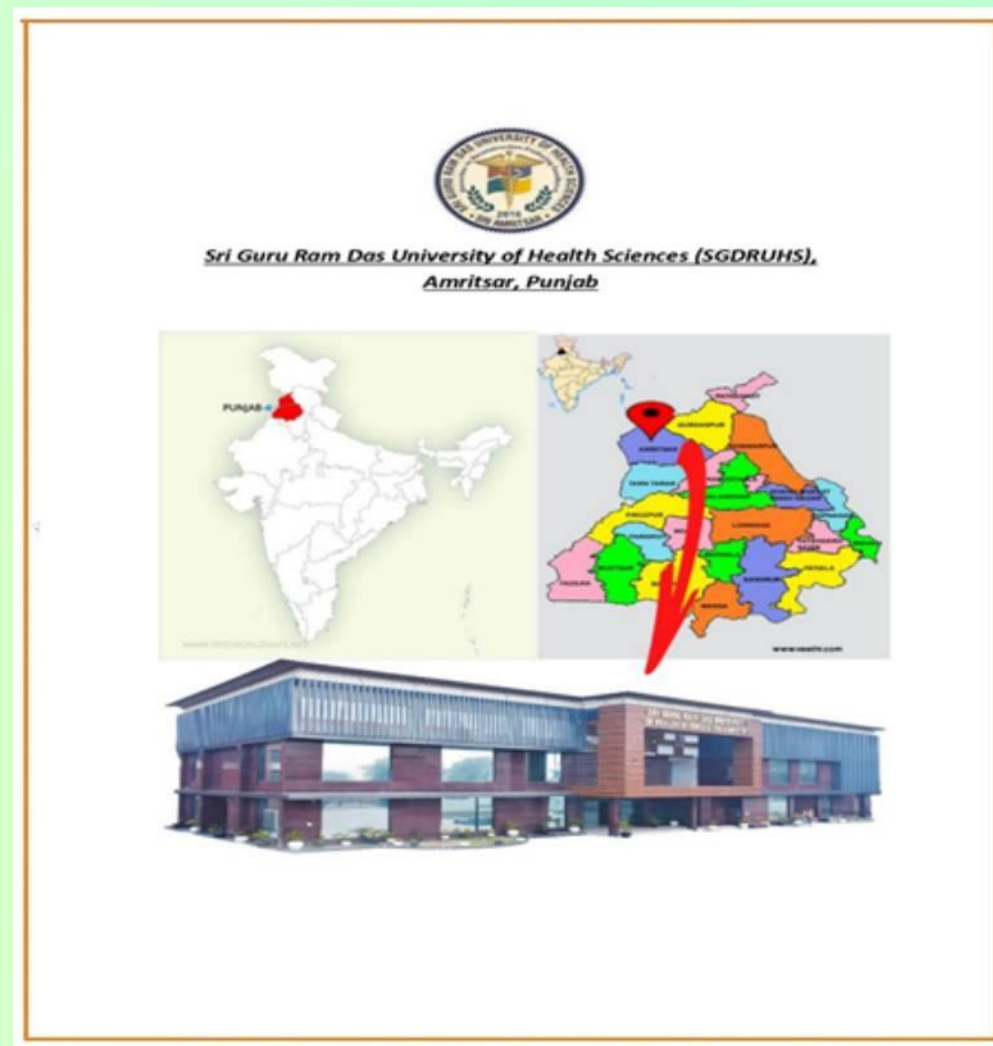
Background of the Site

- Sri Guru Ram Das University of Health Sciences (SGRDUHS), located at Sri Amritsar, Punjab is an outstanding academic institute dedicated to produce exemplary doctors, nurses, health care professionals, academicians, and researchers.
- SGRDUHS is a deemed university declared on 19th August 2016.
- 765 bedded hospital. IPD – 45493 (Av daily 151.64) & OPD 471923 (Av daily 1573.07)
- Added to this 1000 bedded SGRD Charitable Hospital Vallah, Cancer Institute and one primary rural health centre and one urban health centre are the epicentre of comprehensive quality health care services to rural, needy, marginalized and underprivileged population.

Key Capabilities/Strength

- Experienced and dedicated team of PI, PM, CRC, Biostatistician, Nurse, Medical officer and Data entry operator. Clinical research team is trained in GCP, NDCT rules ICMR guidelines for conducting Clinical Research.
- NABL accredited laboratory for clinical investigations. NABH accreditation process is ongoing.
- IEC registered with DCGI. Research is conducted under strict regulatory and GCP guidelines.
- Site is ready with established infrastructure for Clinical Research Centre.
- Galvanising support from management, administration and community in short period of time.

Geographical Location / Catchment Area



Name of the Site: North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences (NEIGRIHMS) , Shillong, Meghalaya
PI: Dr. Prasanta Kumar Bhattacharya/+91 9435030138/pkbdr78@gmail.com

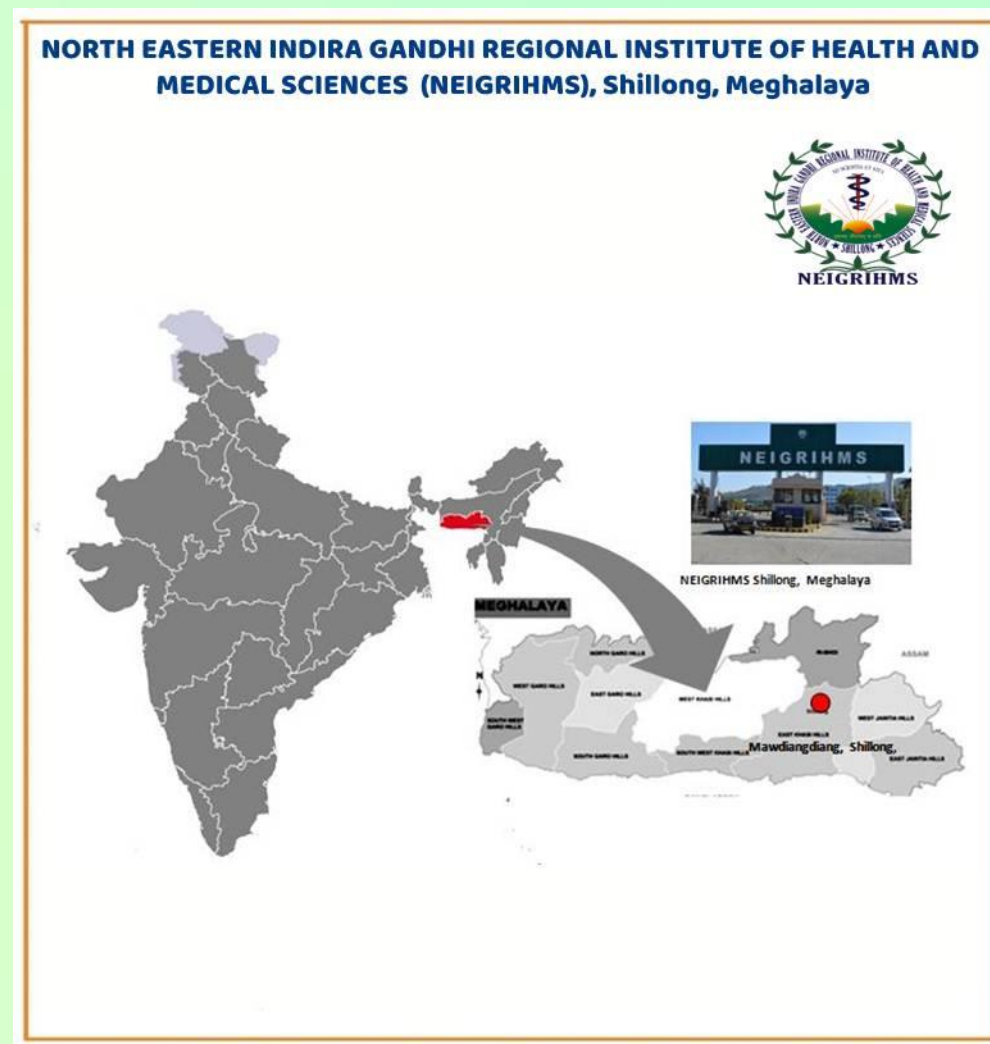
Background of the Site

- NEIGRIHMS is a tertiary care medical institute established by Government of India in 1987, being registered as an Autonomous Institute.
- Site has both In-patient (531 beds + 53 ICU beds) and OPD services for various broad speciality and super-speciality departments, including telemedicine services under the Regional Centre for Telemedicine.
- Only institute to have state-of-the-art Viral Diagnostic Laboratory (VDL) in the NE region besides having high-end molecular pathology laboratory.
- Involved in various multiple multi-centric extra mutual funded projects.

Key Capabilities/Strength

- One of the key hospitals that caters to the population of the North Eastern region and adjoining neighbouring countries.
- The team (Medical Officers, Quality Managers, CRC's, Research nurse and Data Entry Operator) are well experienced and trained in GCP.
- The institute conducts High-end diagnostics and medi-care in Interventional Cardiology, Open Heart Surgery, Neurology, Neurosurgery, Minimal Access Surgery and Hybrid Procedures and Endovascular Interventions with CT-guided Interventional Radiology besides operating microscopes, ECMO, video-endoscopic, laparoscopic facilities in General Surgery, Internal Medicine, Orthopaedics, Obstetrics & gynaecology, Otorhinolaryngology, Ophthalmology, Critical Care Medicine, Emergency Medicine and Resuscitation, Urological
- Surgery besides state-of-the-art medi-care in all other specialities like Joint Replacements, Arthroscopy, GI Endoscopy, Laser Photo Coagulation, Immuno-histo-chemistry.
- The institute has its own DCGI registered Independent Ethics Committee which is supporting clinical trials.

Geographical Location / Catchment Area



Name of the Site: SRM Institutes for Medical Science (SIMS), Chennai, Tamil Nadu

PI: Dr Ravi kiran / 9790869797/ vmravikiran@yahoo.co.in/ drravikiran.m@simshospitals.com

Background of the Site

- SRM Group, well-known for their educational forays had established a 1220 bed hospital at Kattankulathur near Chennai as part of healthcare education and healthcare services.
- SIMS Hospitals a 345 super specialty hospital with 9 Specialty Institutes, offering Institute centric patient care.
- Outreach Clinics are one of the strengths for good patient pool for clinical trials in specialties like Diabetology, Endocrine, Internal Medicine, Oncology, Nephrology, Neurology, Gastroenterology and Obstetrics and Gynecology (OG).
- Committed to creation of knowledge through research across all academic disciplines. Focus areas include Nanotechnology, Bio engineering, Info, Energy, Environment, Materials and Embedded systems.
- SRM Research Institute, a Unit of the university, has been established to catalyze proactive applied research to help solve industry's technical problems and is positioned to address and contribute to the market and society needs.

Key Capabilities/Strength

- SIMS is one of the site of the multicentre project granted by NBM/BIRAC titled “Clinical Trial Network for hospital-based trials in Diabetology”
- Well experienced and GCP trained team (Medical Officers, Quality Managers, CRC’s, Biostatistician, Research nurse and Data Entry Operator) ready to conduct clinical trial
- CDSCO and DHR registered Institutional Ethics Committee.
- Elaborated Site and IEC SOP for ethical conduct of Clinical Trials.
- Well-equipped calibrated equipment’s, storage for IP and exclusive archival for Clinical Trial facility.
- The site is conducting 3 multi-national, multi-centric clinical trials and 7 Indian regulatory trials including COVID related trials. Also, there is an ongoing diabetes trial at the site.

With over 50 collective years of research experience including Diabetology the team is ready to take up clinical trials related to the field of Diabetology.

Geographical Location / Catchment Area



Name of the Site: Institute of Post Graduate Medical Education & Research (IPGME&R), Kolkata, West Bengal

PI: Prof. Dr. Sujoy Ghosh/+91 9674625823/drsujoyghosh2000@gmail.com

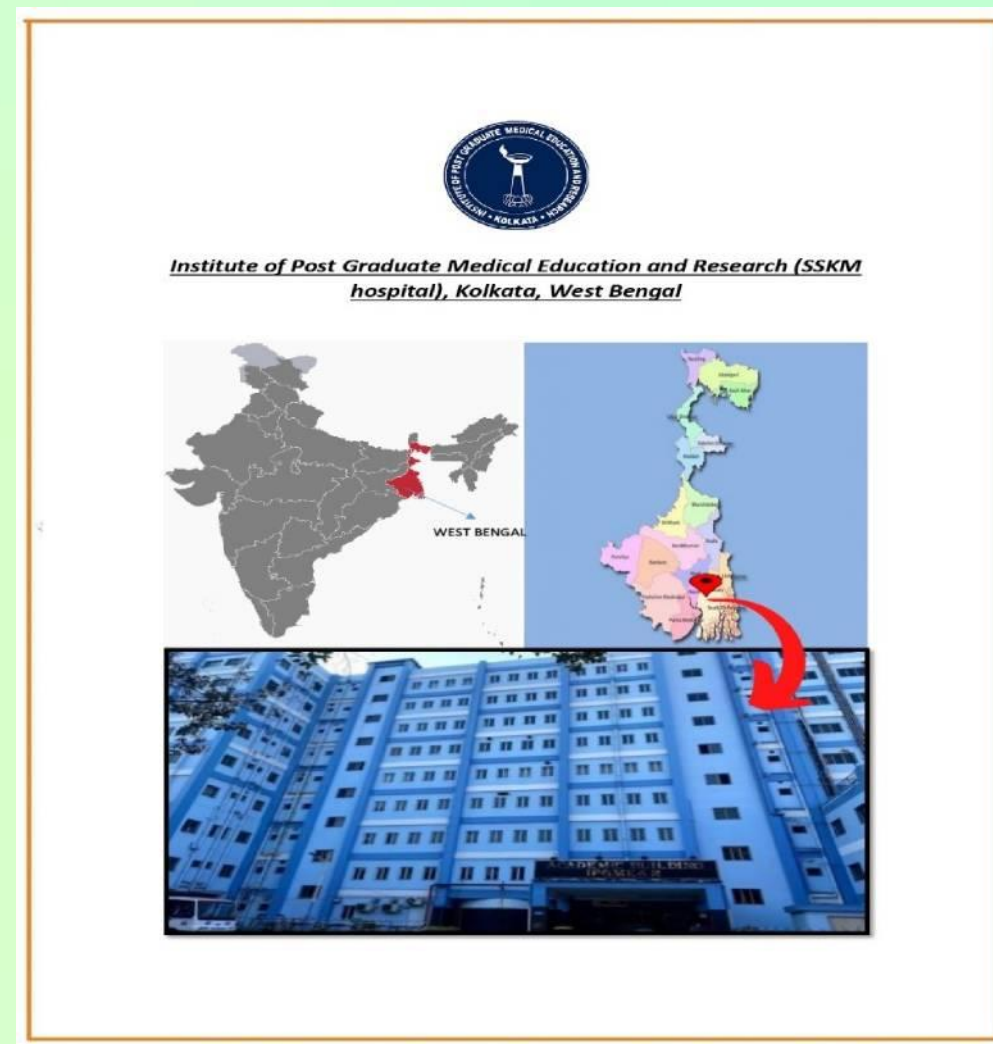
Background of the Site

- IPGMER and SSKM Hospital is a government medical college, tertiary referral government hospital and national research institute.
- This hospital has a glorious record of fundamental research in Medicine. Dr. Ronald Ross has received Noble prize in Medicine for his seminal work in Malaria transmission. The other renowned research outputs came from Edward Hare, D.D. Cunningham, T. H. Lewis, and Ronald Martin.
- Being the apex and the largest tertiary care hospital in eastern India with a bed strength of more than 1400 beds and is the top academic institute of Eastern India, with all medical sub-specialities.
- The Endocrinology and Diabetes OPD serves nearly 1500 people on a daily basis which is the resource for the training and research for the department
- Completed clinical trial projects running in hundreds in the last decades.

Key Capabilities/Strength

- GCP trained, dedicated energetic staff as well as highly experienced Investigators & Research Staffs ready to take up new challenges.
- The Endocrinology department was one of the earliest one established in the whole country has an established research team since the beginning, which in addition to the basic research also an expert in the industry sponsored clinical trials.
- Has completed nearly 40 international GCP clinical trials in the last 2 decades.
- DCGI registered Independent Ethics Committee to support clinical trials.

Geographical Location / Catchment Area



Rheumatology

The aim is to create a network of Rheumatology centres and research institutes across India with the mandate of establishing uniform research standards in compliance with best practices to ensure faster, cost-effective drug development in Rheumatology. Under BIRAC NBM grant, GCP compliant network is being established by utilising trained manpower, procurement of equipment's, establishment of common software for Rheumatology database. Medanta Institute of Education and Research is leading the network with 5 other collaborators (3 private sites- Centre for Arthritis & Rheumatism Excellence, Kerala, St Johns National Academy of Health Sciences Bangalore & Kusum Dhirajlal Hospital Ahmedabad, Gujarat and 2 public hospitals- Post Graduate Institute of Medical Education & Research, Chandigarh & Mahatma Gandhi Institute of Medical Sciences, Sevagram, Maharashtra). The aim is to develop harmonised research processes in compliance with GCP for faster and cost effective conduct of clinical trials. Electronic database for registry of various Rheumatology diseases such as Rheumatoid Arthritis, Psoriatic Arthritis, Spondyloarthritis, Myositis, Sjogren's syndrome, Systemic lupus erythematosus, Systemic sclerosis, ANCA associated vasculitis, Aortoarteritis is being created on a common IT platform to support GCP compliant clinical trials in Rheumatology. Common protocol for establishing database has been established among all centres and approved by Institutional Ethics Committee.

MEDANTA Rheumatology Network (6 sites)



Name of the Site: Medanta Institute of Education and Research (MIER), Gurugram (Haryana)

PI: Dr. Rajiva Gupta /+91 9810904592/ rajiva.gupta@medanta.org

Background of the Site

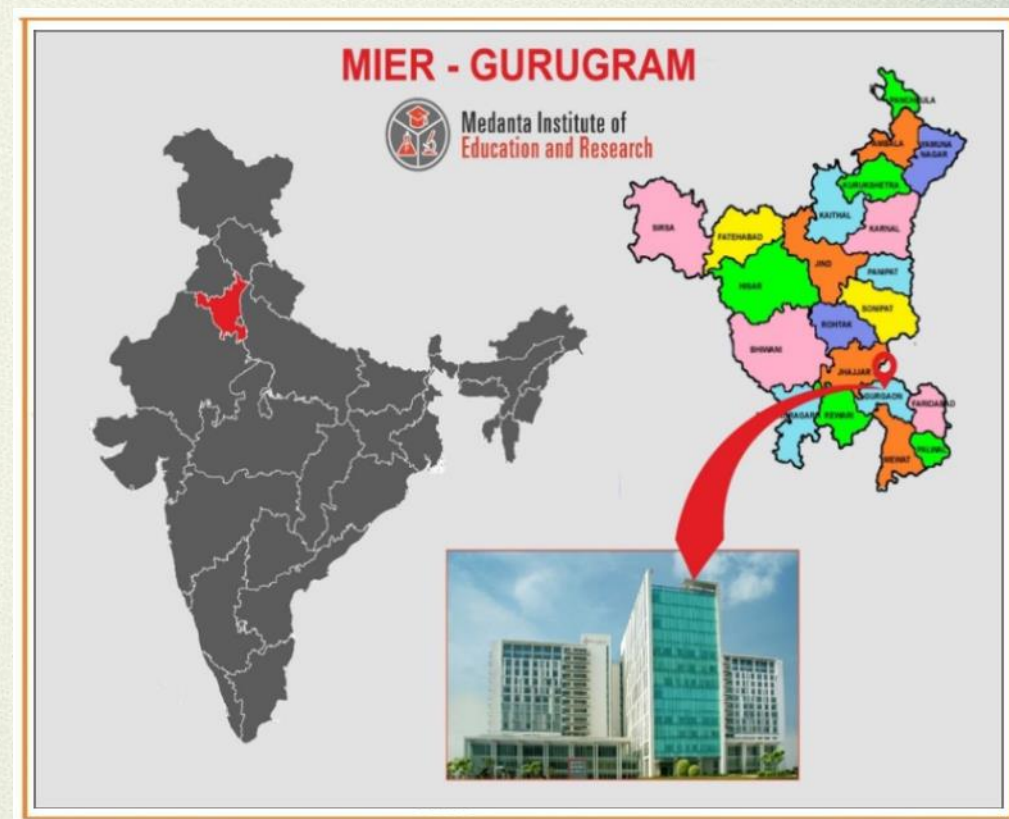
- MIER is a DSIR recognized Clinical Research Unit established in 2011 and nested within NABH and JCI accredited super specialty hospital, Medanta-The Medicity with 1250 beds, over 800 experienced doctors and 29 super specialties.
- Site has a 60 bedded Proof of Concept facility with adequate space for subject recruitment activities such (screening, medical examination, AV consenting, Access controlled pharmacy, sample collection and archival MIER works closely with the Medanta Lab (NABH and NABL) for core lab services and tissue repository.
- Regulatory and patient protection oversight is provided by a DCGI and DHR Registered Ethics Committee MIEC (**DCGIECR/282/INST/HR/2013/RR-20**) (**DHR-EC/NEW/INST/2020/633**) with a Federal Wide Assurance and OHRP (**IORG0006315**).
- Well established e-HIS (Electronic Hospital information system), e-CRMS (Electronic Clinical Research Management System) and VDMS (Volunteer Data Management system).
- Large cohort of patients with various autoimmune rheumatology diseases visit at site..

Key Capabilities/Strength

- Experienced site team in conducting interventional regulatory trials, academic trials and large public health research studies with special expertise in conducting Phase I studies in healthy volunteers and patients.
- Quality Management System with SOPs, Institutional policies and Manuals for conducting Phase I to phase IV studies.
- An access-controlled pharmacy for handling and storage of investigational products at 2-8°C and room temperature (15-25°C), cabinets with locking facility with 24 hours power backup, alarm systems, temperature monitoring, calibration and regular maintenance of instruments

- Center has a volunteer data base of approximately 7280 healthy volunteers, and a strong outreach. **Volunteer data base** of approximately 7280 healthy volunteers, and a **strong outreach with universities, RWA, corporates** and also works closely with **several NGOs** (Iamgurgaon, DLF Foundation etc), and the **Municipal authorities**.
- Since inception successfully completed approximately 1129 studies including clinical trials, academic studies, Investigators initiated studies and other public health and student research.
- 03 Rheumatology trials are on-going at site and 03 are in start-up phase

Geographical Location / Catchment Area



Name of the Site: Mahatma Gandhi Institute of Medical Science (MGIMS), Sevagram, Maharashtra.

PI: Dr. Bharati Taksande / +91 9881017505/Bharati.taksande@gmail.com

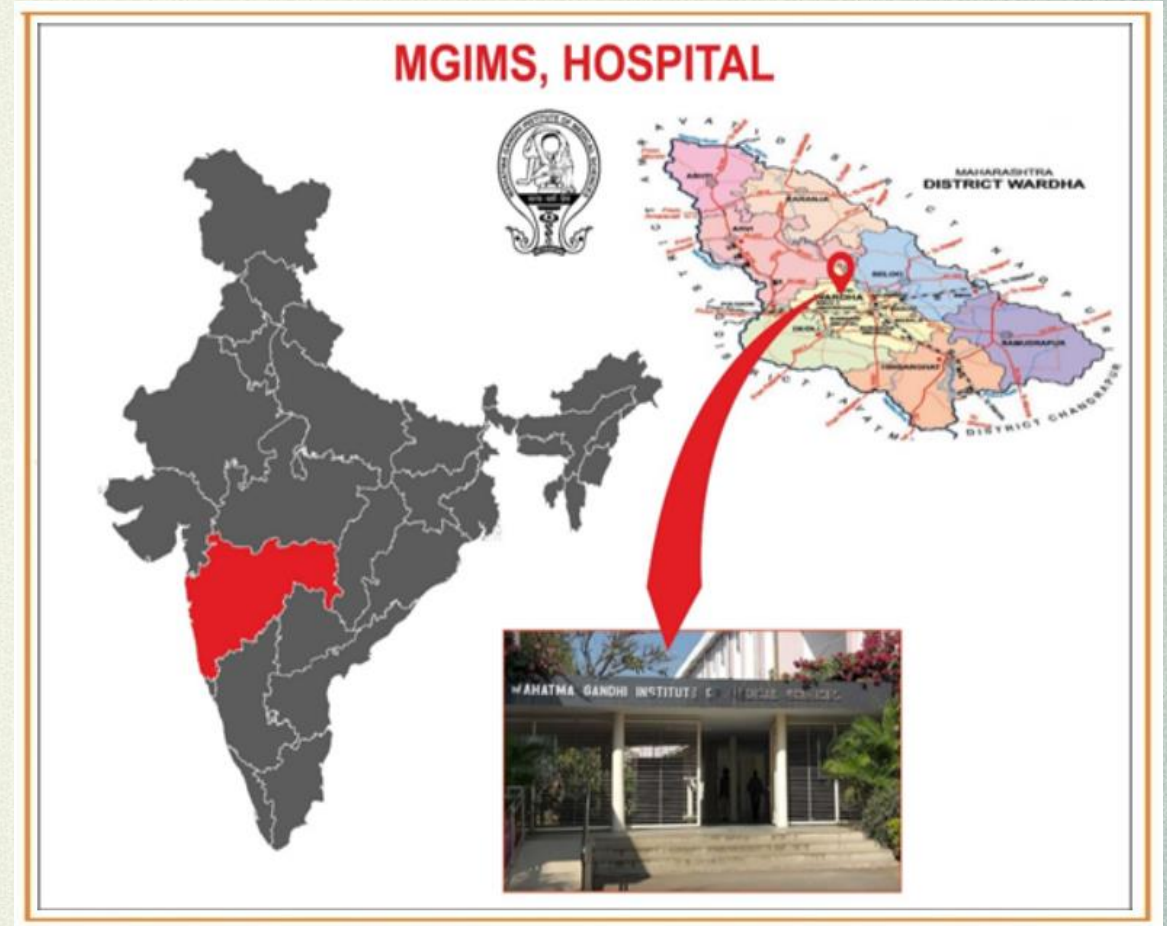
Background of the Site

- MGIMS India's first rural medical college managed by the Kasturba Health Society was established in 1969 at Sevagram, Maharashtra.
- Independent India's first attempt to give a new direction to rural health. From a mere 15 bedded hospital to its 974 beds and a hospital with state-of-the-art facilities with an average daily footfall of 1,500 OPD patients.
- The institute nursing the rural community with nominal fees and implemented the concept of health insurance in rural areas. Working towards its community-oriented mission by working strongly with its alcohol and drug de-addiction centre.
- Experienced site in community-based research conducted in areas like maternal, neonatal, and child health care, infectious diseases, nutritional illnesses, lifestyle, and disorders. Site has experience in Meningococcal ACYWX Conjugate Vaccine, r-BCG vaccine, Liquid Rota virus.

Key Capabilities/Strength

- CDSCO and DHR registered Ethics Committee for Clinical Trials/study.
- Established Electronic Hospital information system e-HIS, paper CRF, archival facility and project specific cabinets for ongoing research project to maintain patient records.
- Laboratories are dedicated to provide quality service with the help of high calibre trained and experienced Consultant staff. Equipped with state-of-the-art analysers and systems to enable the provision of a robust and reliable daily diagnostic service like Haematology, biochemical, rheumatology, pathology, cytology, microbiology, mycology, histopathology, bacteriology, mycobacteriology, toxicology, cytogenetics, physiology, Radiology. The NABL accreditation of clinical laboratory is under process.
- One rheumatology clinical trial is ongoing.

Geographical Location / Catchment Area



Name of the Site : Centre for Arthritis and Rheumatism Excellence (CARE), Kerala

**PI: Dr Padmanabha Shenoy/ +91 9446567000/
drshenoy@drshenoycare.com**

Background of the Site

- CARE founded in 2014, with a simple moto "Live pain free "has now grown as one of the largest Rheumatology centre in India.
- Expert team of doctors include Rheumatologists, Orthopedicians, Musculoskeletal Radiologists, Psychologists, Psychiatrists, Clinical pharmacists and Physiotherapists under one roof
- CARE is Rheumatology Clinic with a daily OPDs with a patient pool of about 350 to 400 patients. IP facilities in SSMM (Sree Sudheendra Medical Mission Hospital) with 30 beds under Rheumatology department only.
- Special clinics, physiotherapy department and psychologist/counsellor with customised individual treatment protocol for each patient to manage illness with increase chances of living a normal pain free life.

Key Capabilities/Strength

- Qualified research team trained in ICH GCPu and patient pool to undertake clinical trial.
- Institutional Ethics Committee (IEC)-registered with CDSCO and DHR.
- The site has NABH accredited clinical laboratory, MOU has been signed with NABL accredited lab. Autoimmune laboratory equipped with the latest technology.
- Separate Pharmacy facility and well-maintained Archival area.
- Conducting RA, PSA, AS, Lupus clinics at CARE, - Awareness class and doubt clearance for each clinic is conducted on a weekly basis. Educational videos are played, brochures and handouts are distributed among patients. Patients get services of other allied specialists like clinical pharmacists, physiotherapists, psychologists apart from the routine rheumatology consultation.
- In co-ordination with ASIF - Ankylosing spondylitis India Federation (ASIF) and LUPUS trust India, CARE conducts awareness talks, campaigns to spread awareness and provide long term and affordable medical treatment, while also extending community support to the patients and their caregivers Community engagement program.

- Remote Patient care through teleconsultation during COVID pandemic.
09 Rheumatology trials (academic) are on-going at site.

Geographical Location / Catchment Area



Background of the Site

- Established in May 2018 KD Hospital is NABH accredited super specialty 300 bedded hospital with a group of committed staff and versatile cohort of around 90 doctors and 45 super specialties situated at prime location of Ahmedabad, Gujarat.
- Recently established (Jan 2020) Clinical Research department has adequate space for subject recruitment activities such as (screening, medical examination, AV consenting, sample collection), archival room and an e-HIS (Electronic Hospital information system). It works closely with the KD hospital pathology Lab (NABL accredited) for core lab services.
- Under BIRAC NBM grant, KD hospital is a part of establishing GCP compliant network. KD hospital is a new site having collaboration with experienced sites in establishing SOP's, training of manpower and procurement of equipment.

Key Capabilities/Strength

- As a part of CTN site has recruited team which consists of Sr Research Associate, CRC, QA, Data entry operator, lab technician, Medical officer and Investigators who are GCP trained, dedicated and experienced in conducting interventional regulatory trials, academic trials and large public health research studies.
- Regulatory and patient protection oversight is provided by a DCGI and DHR (applied) Registered Ethics Committee KDIEC(ECR/1294/Inst/GJ/2019) KDAEC (EC/New/Inst/2021/1815).
- Quality Management System with SOPs, Institutional policies and Manuals for conducting Phase I to phase IV studies are being developed along with other CTN sites.
- NABL accredited lab for various investigation in Haematology, Pathology, Biochemistry, Immunology, Serology and Microbiology.

- Establishment of an access-controlled pharmacy for handling and storage of investigational products at 2-8°C and room temperature (15-25°C), stability chamber, Refrigerator, Deep freezer, Normal and cold centrifuge, cabinets with locking facility with 24 hours power backup, alarm systems, temperature monitoring, calibration and regular maintenance of instruments are in process.
- 2 Ongoing trials of complicated urinary tract infection and bacterial pneumonia and 5-6 regulatory trials of different indications are yet to start.

Geographical Location / Catchment Area



Name of the Site

St. John's National Academy of Health science (SJNAHS), Bangalore

PI: Dr Vineeta Shobha/ +91 9845021146/ vineeta.s@stjohns.in

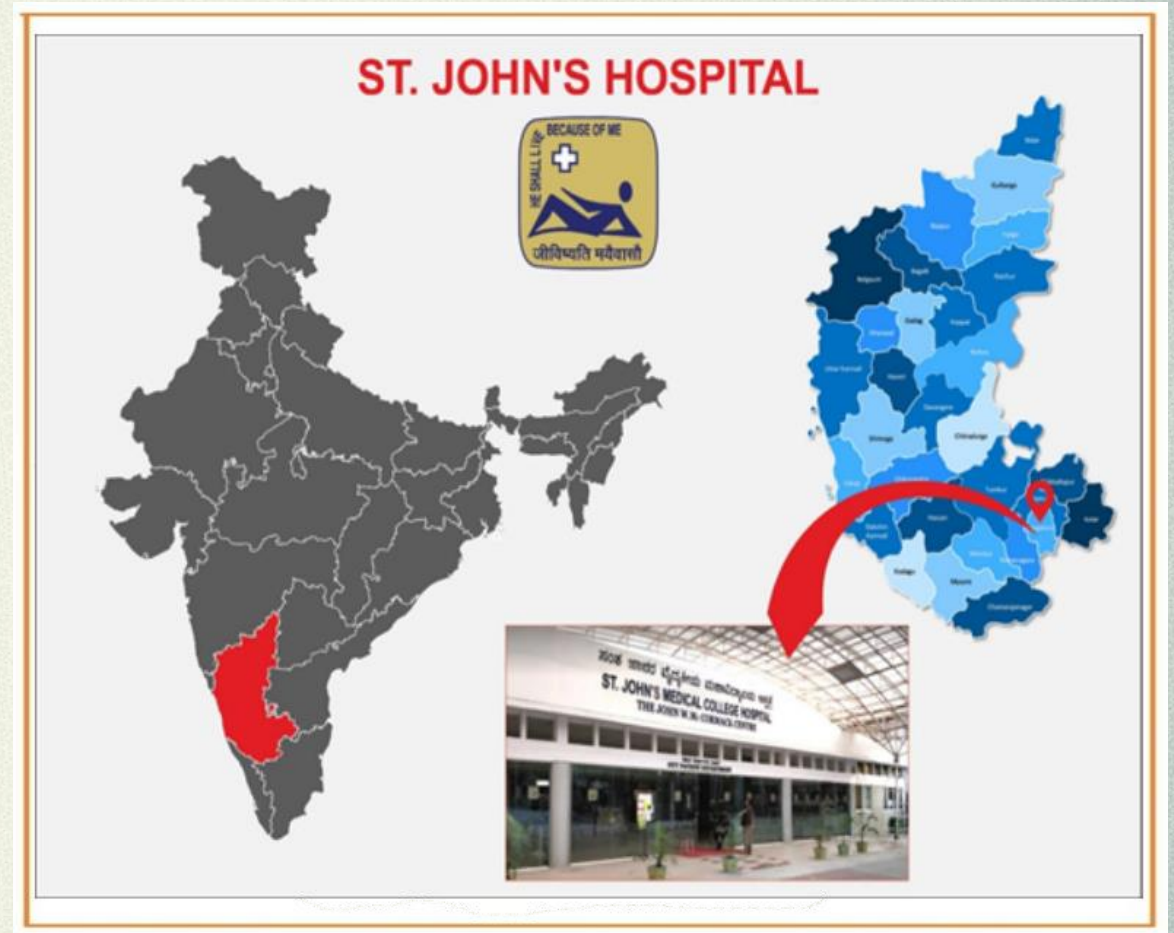
Background of the Site

- St. John's National Academy of Health Science (SJNAHS) is a tertiary-care, referral and teaching hospital
- The Academy has been functional for almost more than 4 decades, catering to large populations from all surrounding states of Tamil Nadu, Andhra Pradesh, Telangana, Kerala etc. apart from Karnataka.
- Provides ethical and professional clinical care and treatment across all specialties ably supported by diagnostics services including laboratory-based imaging and interventional facilities.
- SJNAHS, NABH accredited with 2000 inpatient beds.
- The site is associated with 375 rural health centres.
- Well established Division of Clinical Research and Training (DCRT) to design and conduct large national and international clinical trials and observational studies in cardiovascular disease (CVD), diabetes and infectious diseases.

Key Capabilities/Strength

- Centre provides **emergency, outpatient, inpatient, day-care, community outreach, pastoral and after-life care.**
- Experienced site team in conducting interventional regulatory trials, academic trials and large public health research studies.
- CDSCO and DHR registered IEC.
- Quality Management System with SOPs, Institutional policies and Manuals for conducting Phase II to phase IV studies.
- In-house NABL accredited labs for clinical investigations in Hematology, Biochemistry, Microbiology, Pathology, Radiology and basic Immunology.
- Completed more than 200 DCGI regulated national and global trials; Phase I-Phase IV in various fields of medicine and enrolling over 700 participants. 04 industry sponsored clinical trials for Rheumatology indications are on-going at site and >25 industry sponsored international clinical trials for various indications over the last 15 years.

Geographical Location / Catchment Area



Background of the Site

- PGIMER has been adjudged as one of the best institutes for medical education with the best research facilities amongst the multispecialty hospitals in India.
- Conferred two Federation of Indian Chambers of Commerce and Industries (FICCI) Healthcare Excellence Awards for the year 2014 under the categories of Medical Technology and Diagnostics, Pathology Laboratories.
- The new 250 bedded expansion of Nehru hospital is ready to cater the needs of the ailing humanity covering not only the northern states but all other states of the country
- Successfully completed over 200 DCGI regulated trials phase I-IV in various fields of medicine enrolling over 500 participants, with 7 trials an over 20 patients in rheumatology.

Key Capabilities/Strength

- Undertake Basic Community based research with high quality Patient care.
- Well established site with GCP and bioethics trained manpower.
- Ongoing Rheumatoid Arthritis registry since 2018 with serum sample collection.
- Well established Electronic Hospital information system e-HIS, paper CRF through computers, phones and hand-held devices and analysis using SPSS & R software.
- Dedicated consultation rooms with audio visual consenting. Third party archival facility is also available at site.
- Equipped with NABL accredited clinical investigation lab and CDSCO &DHR registered IEC.

Geographical Location / Catchment Area



NATIONAL BIOPHARMA MISSION

Industry-Academia Collaborative Mission for
Accelerating Discovery Research to Early
Development For Biopharmaceuticals-

**“Innovate in India (i3) Empowering
biotech entrepreneurs & accelerating
inclusive innovation”**

