Micro Therapeutic Research Labs Private Limited

Science with Ethics

INTEGRATED SERVICE PROVIDER FOR PHARMA & BIOTECH COMPANIES

- MTR was founded in Chennai, India in the year 2005 with a vision "To be amongst the top five healthcare research organizations globally"

- MTR is a full service Contract Research Organization supporting global Pharmaceutical, Biotech and Cosmetic industries in the bio analytical, clinical and preclinical research areas

- MTR has three comprehensive, state-of-the-art facilities, spreading over 86,000 sq.ft. and, is established as a centre of excellence for conducting BA/BE Studies & Clinical Trials

Robust quality systems with continuous improvements in adherence to GCP and GLP

10 years Successful partnering to research industry in the field of

Clinical BA/BE (Small and Large molecule):-

- More than 1400 BA/BE studies done for Indian and International Pharma/Biotech companies
- More than 200 studies on 'Contraceptives' and Hormone molecule for female
- More than 2800 protocols prepared
- Major Indications/Therapeutic segments handled in BA/BE and Clinical Trial are Hypertension, Insomnia, Cholesterol, Psychiatrics and Parkinson's disease and Oncology
- **Route of Administration:**- Oral, Transdermal, Sublingual, Intra vaginal, Intravenous and Sub-cutaneous etc.,

To be continued……

Clinical Trial:-

- Successfully completed 20 trails out of which 12 studies on Oncology and 8 studies in Diabetics, Infections and Neutrional
- It has tie up with 50 Hospitals across India

Pre-Clinical:-

- 250 studies on toxicity, toxicokinetics, pharmacology and pharmacokinetics
- Special studies like Bone Implantation, Ocular kinetics and Sublingual

Bio-similar :-

- Completed physico chemical characterization for 2 large molecules
- Developed and validated method for immunogenicity and Pharmacokinetics assays for 6 large molecules

- MTR is engaged in clinical research for Phase I to IV Trials
- MTR offers Clinical Research Services (CRS) including Clinical Trial Project Management, Biostatistics and Data Management, Clinical Pharmacology and Site Management Services
- **MTR has a dedicated team** of around 28 personnel for Phase trials
  - GM- Clinical – 1
  - Medical Monitor - 1
  - Project Managers – 4
  - QA Managers - 2
  - Clinical Research Associates -10
  - Research Nurses & Coordinators -10

SERVICES

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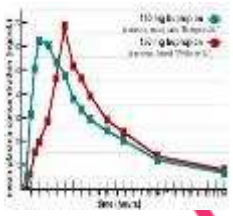
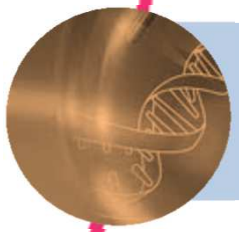


Bioavailability & Bioequivalence

Biological



Clinical Research

Non-clinical

KEY PERSONNEL

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NAME	AFFILIATION	DESIGNATION	YEAR(S) OF EXPERIENCE
Dr. M. Ganesan	Scientist	Managing Director	20
Mr. N. Sundar	Finance	Chief Operating Officer	18
Ms. R. Abiraamasundari	Scientist	Director-QA and Regulatory affairs	11
Dr. K. Senthil Kumar	Principal Clinical Investigator	General Manager	06
Dr. K. Susheela Branham	Scientist	Manager-Clinical Trial	09
Mr. Ajay Kumar Mishra	Scientist	Manager - QA	10
Ms. G. Vasanthi	Administrator	Manager - Project Management	08
Dr. L. Hari Babu	Scientist	Team Leader – Report Writing	06
Mr. K. Nehru	Scientist	PK & STAT Investigator	06
Mr. N. Medhavi	Scientist	Head - Diagnostics	22

ORGANOGRAM FOR CLINICAL TRIALS DIVISION

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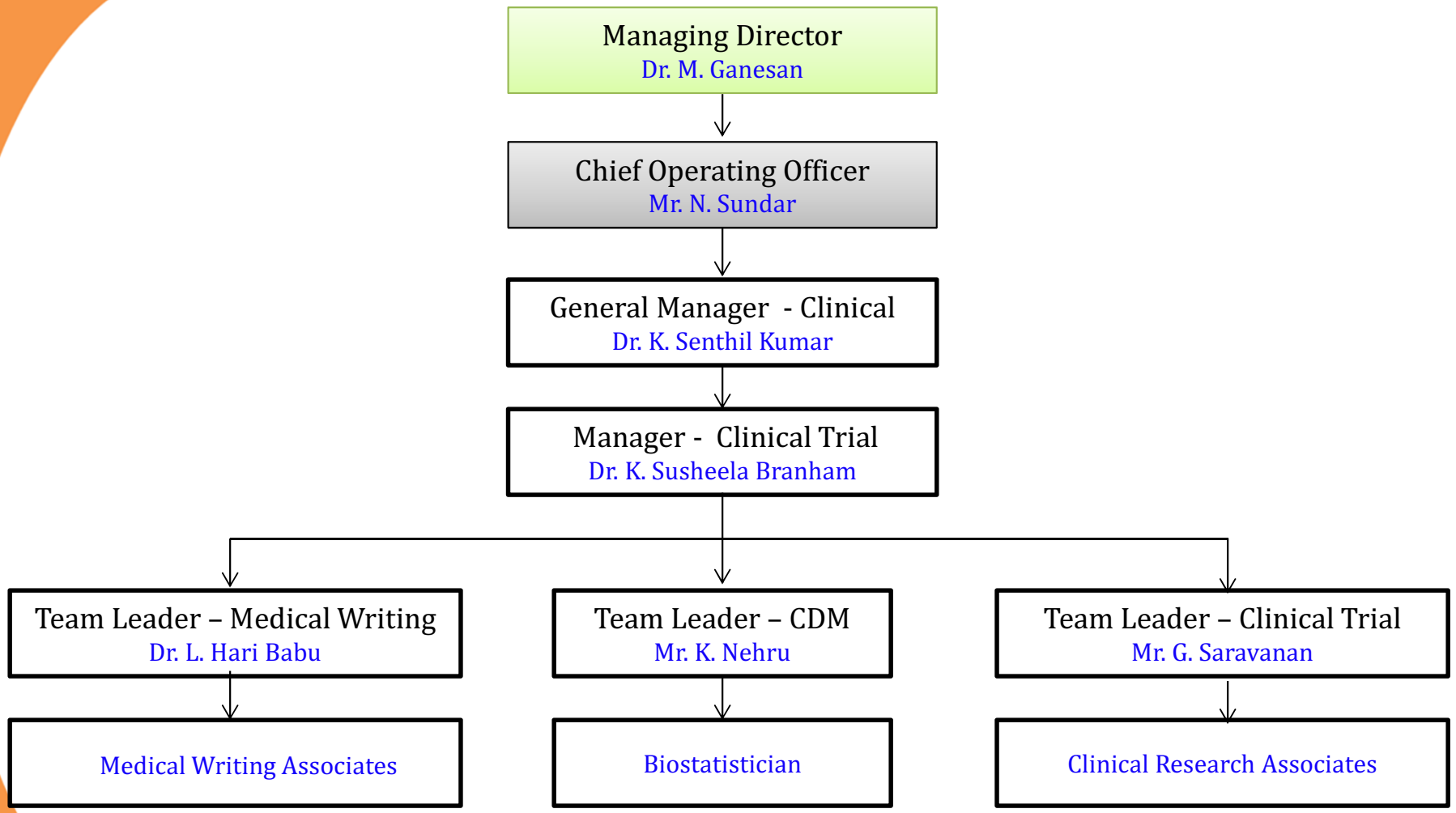

REGULATORY AUDITS & ACCREDITATIONS

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FDA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

cap ACCREDITED™

NABL

ANVISA

World Health Organization

सत्यमेव जयते
DSIR

CPCSEA
Committee for the Purpose of Control and Supervision of Experiments on Animals

afssaps
Agence française de sécurité sanitaire des produits de santé

ansm
Agence nationale de sécurité du médicament et des produits de santé

BfArM

REGULATORY AUDITS STATUS

REGULATORY	PHASES	YEAR	STATUS
ISO 9001:2000	Systems Audit	2006	Certificate received
NABL	System & Quality Audit	2008	Certificate received
US FDA	Clinical audit	2009	No Findings
DCGI	Facility audit	2009	Facility approved
AFSSAPS (ANSM)	Clinical & Bio Analytical	2010	Approval received
US FDA	Clinical & Bio Analytical	2010	EIR report received
ANVISA	Facility Audit	2010	Approval received
US FDA	Clinical	2011	No Findings
ISO 9001:2008	Systems audit	2011	Certificate received
CAP	System & Quality audit	2011	Certificate received
US FDA	Clinical Trial	2011	No Findings
WHO	Clinical & Bio Analytical	2011	Approval received
DCGI	Facility Audit (Coimbatore)	2011	Facility Approved
US FDA	Clinical	2012	No Findings
ANVISA	Facility Audit (Coimbatore & Chennai)	2012	Facility approved/Reapproved
ANSM/ BfArM	Clinical & Bio Analytical	2013	Report Received
ANVISA	Facility Audit (Chennai)	2013	Facility Reapproved
DCGI	Facility Audit (Coimbatore & Chennai)	2013	Facility Reapproved
US FDA	Clinical Trial	2013	EIR awaited
NABL	System & Quality Audit	2013	Certificate received
DCGI	Facility Audit (Chennai)	2014	Approval awaited

REGULATORY & ACCREDITATIONS - HISTORY

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REGULATORY	PHASES	YEAR	STATUS
CAP	System & Quality audit	2015	Certificate received
US FDA	Clinical	2015	Awaiting for EIR
NABL	System & Quality Audit	2015	Certificate received
US FDA	Bio Analytical	2015	Awaiting for EIR
ISO 9001:2008	Systems Audit	2015	Certificate received
US FDA	Clinical & Bio analytical (Chrompet)	2015	Nil 483
DCGI	Facility Audit (Chrompet)	2015	Renewal Certificate received
US FDA	Clinical (Coimbatore)	2015	Nil 483

FACILITIES

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MTR, Selaiyur

MTR, Coimbatore

MTR, Chrompet

MTR, Padi

MTR, Selaiyur, Chennai, IN

- Spread over 40,000 square feet of area
- CPU with 55 beds
- Bio-analytical lab with 12 LC-MS/MS and 1 ICP-MS instrument and Ion Chromatography instrument
- 24 Hours power back up with UPS support

MTR, Coimbatore, IN

- Spread over 45,000 square feet of area
- CPU with 100 beds
- 24 Hours power back up with UPS support

MTR, Chrompet, Chennai, IN

- Spread over 21,000 square feet of area
- CPU with 125 beds
- Bio-analytical lab with 08 LC-MS/MS instrument
- 24 Hours power back up with UPS support

MTR, Padi, Chennai, IN

- Spread over 18000 square feet of area
- GLP compliant pre-clinical and biology lab
- 24 Hours power back up with UPS support

OBJECTIVE OF RESEARCH MANAGEMENT SERVICES

Science with Ethics

- To support Sponsors by providing complete Clinical trial management with competent & experienced team of Clinical Research professionals

&

- To ensure the successful outcome of Clinical trials for Pharmaceutical, Biotechnology and Medical device industries with high data quality and reduced timelines

CLINICAL TRIAL–POSITIONING MTR IN INDIA SCENARIO

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INDIA	MTR
Out of 1500 Clinical Trials - 500+ Trials are on Oncology (33%)	MTR has vast experience of trials on **Oncology Products**
Most of the PK trials are on cancer patients	MTR has good experience in PK studies on Oncology and it has more than **30 Oncology sites, 10 Diabetic sites, 10 Psychiatry sites** across India
Phase trials percentage wise ➢ Phase IV-12% ➢ Phase III -60% ➢ Phase II-20% ➢ Phase I-5%	Experience in conducting all the **phases in Clinical Trials**
Number of trials State wise 350 trials in Bangalore (23%) 370 trials in New Delhi (25%) 200 trials in Chennai (15%) 300 trials in Andhra Pradesh (20%)	MTR has Centers at **Gurgaon(NCR)-7 Km from New Delhi Airport.** **Bangalore & Chennai, Coimbatore & Madurai**

1. Conceptual Phase:-

- Feasibility evaluation
- Protocol synopsis preparation
- Schedule of project management activities to define timeline and resources requirement

2. Planning Phase:-

- Protocol and model ICF are finalized
- Sites are selected
- Operations Manual completed
- CRF's are finalized
- IRB Approvals are obtained
- Site sub contracts/payment schedule in place & Contracts are finalized with third party vendors
- Database is built
- Study drug packaging/labeling is finalized

3. Implementation phase

- Enrollment of subjects
- Distribution of study drug to sites
- Protocol/CRF queries are resolved
- Monitoring activities in place
- Incident calls are noted like;
  - SAE's
  - Dosage adjustments
  - Premature withdrawals
  - Drug Disclosure
- Data query process in place
- Data base is cleaned/closed
- Database is transferred to Biostatistics

4. Analysis and Publication Phase

- Primary/secondary analysis is performed
- Abstract is submitted
- Manuscript is submitted
- CTR is submitted
- Post-hoc analysis is completed

CLINICAL TRIAL PROJECT MANAGEMENT SERVICES

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- Phase I, II, III & IV
- Project plan, Budget Management & Timelines development
- End-to-end coordination i.e. Feasibility-Initiation-Monitoring-Safety Reporting-Close-out-Final study report preparation

FEASIBILITY & STUDY START-UP	MANAGING & MONITORING THE STUDY	STUDY COMPLETION & CLOSE-OUT

CLINICAL MONITORING SERVICES

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Our clinical monitoring teams deliver faster, more efficient

Investigator site support and data oversight

- Medical Monitoring (including 24/7 Medical Monitor coverage)
- Reviews Source documentation and Case Report Forms
- Ensures regulatory compliance
- Clarifies inclusion/exclusion criteria with the Investigator and resolves data queries
- Conduct interim analysis as requested by the clients
- Providing consultation for potential safety issues or medical concerns

REGULATORY AFFAIRS

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Our regulatory team has thorough industry knowledge and hands-on experience in working with different regulatory agencies and is completely equipped to handle Investigational New Drug (IND's), Ethics Committees, DCGI, New Drug applications (NDA's)

- IND/Phase I Clinical Trials
- Phase II, III and IV clinical trial approval for drugs
- Pilot and Pivotal studies for Devices
- Import licenses for investigational products, ancillary supplies and equipment's'
- Export licenses for Biologicals
- Marketing authorization for drugs
- Site and product registration for drugs and devices
- Prepare and coordinate for New Drugs Advisory Committee (NDAC) and Medical Device Advisory Committee at DCGI Office
- Getting approvals from DCGI/IRB Safety reporting

MEDICAL WRITING SERVICES

Science with Ethics

Our Medical Writing services follow ICH guidelines and are compatible with regulatory requirements

- Clinical study protocol development
- Preparation of Investigator Brochure
- Designing of CRF
- Clinical Study Reports
- Preparation of Informed consent/assent forms & back translation in to vernacular languages
- Preparation of Diary cards
- Preparation of patient information leaflets/narratives
- Data Safety Monitoring Board (DSMB updates), regulatory submissions and other documents involving study data

BIOSTATISTICS AND DATA MANAGEMENT SERVICES

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- Sample Size Calculations
- Randomization
- Clinical Trial Design along with CRF
- Statistical Analysis Plan
- Statistical Programming
- Clinical report preparation
- 21 CFR Part 11 compliance
- SAS 9.2,WinNonlin 5.2.1,CDISC Standard
- Report formats (full eCTD / Partial eCTD)

QUALITY ASSURANCE

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Investigative Sites Audit - Covering:

- Trial master file audits
- System audits
- Site audits
- For cause audit
- Central laboratory audits
- Data base audits
- Final clinical report audits

SITE MANAGEMENT SERVICES

Science with Ethics

- Provision of competent Site Coordinator
- Pre-monitoring visit at site to ensure error free data during the sponsor visit
- GCP & Protocol training to the Investigators & site staff
- Complete site management support during the study
- Immediate query resolution and report
- Well designed adoptable patient recruitment & retention methods
- Facilitate Study documents archival

THERAPEUTIC AREAS OF EXPERTISE

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- Oncology
- Hematology
- Dermatology
- Obstetrics and Gynecology
- Neurology/Neurosurgery
- Endocrinology and metabolic Disorders
- Diabetology
- Gastroenterology
- Psychiatry
- Orthopedics
- Cardiology
- Radiology

TODAY'S LIMITATIONS AT SITE

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- Busy investigators - Incomplete IC process with complete ICF documentation
- Lack of awareness about clinical trials even in educated public
- Lack of infrastructure, trained & dedicated professionals at sites
- Lack of active participation & independent decision-making from IRBs & Scientific committees
- Most of the hospitals doesn't have Scientific and Ethics Committees
- Most often investigative site doesn't have SOP's on clinical operations although it's a requirement of Schedule-Y
- Improper reporting of AE/SAE's
- Improper study archival facilities at site

ADVANTAGE OFFERED BY MTR

Science with Ethics

- Dedicated Clinical trial team under professional leadership
- Extensive network of GCP trained Investigators in diversified therapeutic areas
- Partnerships with potential Institutions and Investigators
- Structure contracts with clear unambiguous language and strict adherence to meet costs within budget.
- Patient Recruitment Strategies are part of Project Management and are implemented prior to site initiation
- Provision of clinical trial SOPs pertaining to the study site
- Effective monitoring and audit processes - Provide clear-cut status reports on site performance (monthly basis) by centralized management

ADVANTAGE OF MTR

Science with Ethics

- Conducted 16 clinical trials, both domestic and international
- Successfully completed USFDA audit in the year 2011 for Temozolomide trial conducted at the sites and cleared with Nil 483
- Experienced in conducting BA/BE studies in Oncology
- Has well equipped Bio Analytical Lab
- Shipment of samples is organized by MTR

Ethics Committee:

- MTR will be using the services of site IRB
- All the sites where MTR conducted the study have GCP compliant Ethics committee formed as per ICMR/Schedule Y guide lines

CORE CAPABILITIES

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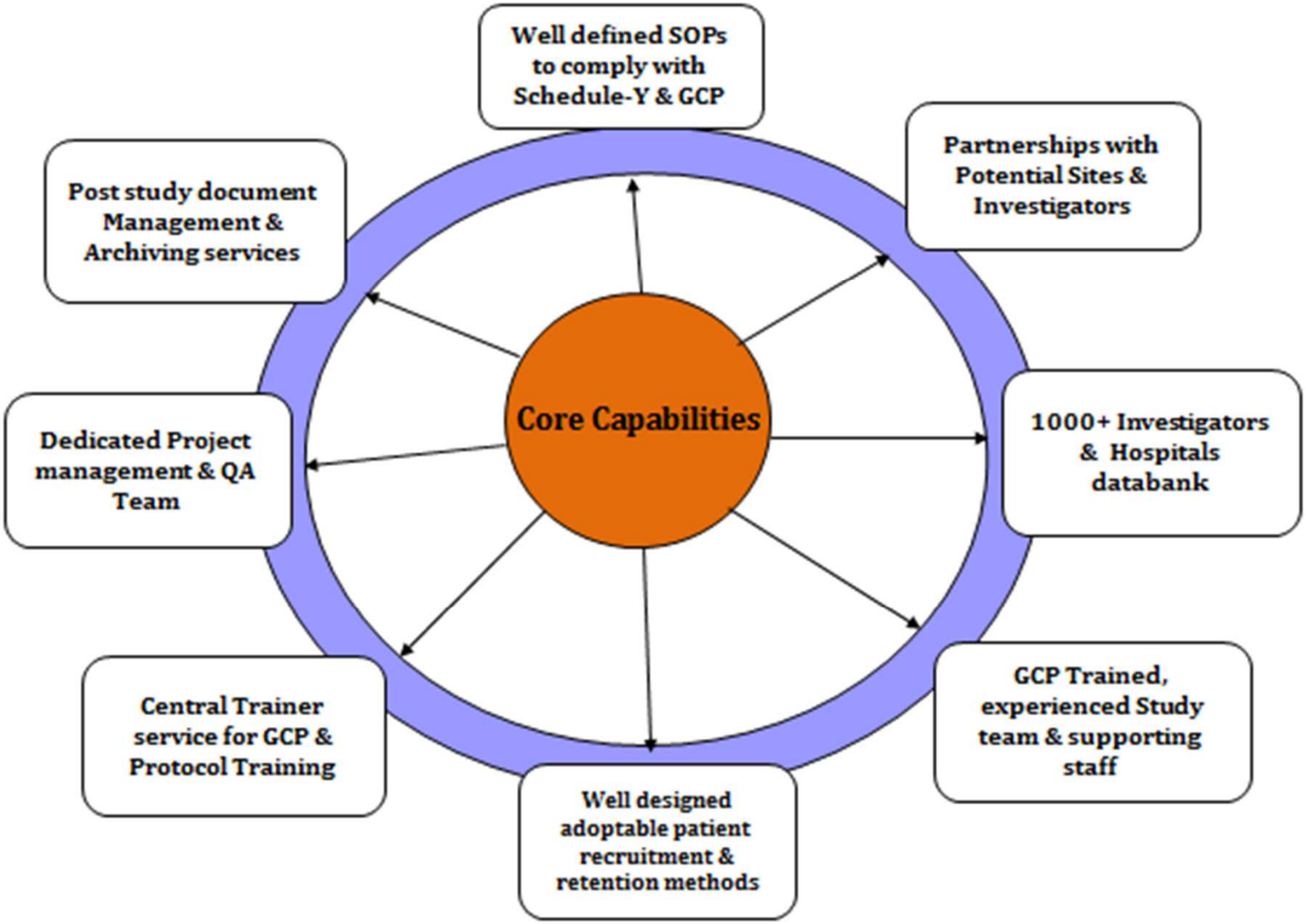

MOLECULES EXPERIENCE

Science with Ethics

Pivotal Studies				
S.NO	**MOLECULES**	**NO. OF SUBJECTS**	**INDICATIONS**	**SUBMISSION**
1.	Doxorubicin Injection	24 Patients	MULTIPLE MYELOMA	EU Submission
2.	Doxorubicin Injection	24 Patients	OVARIAN CANCER	US FDA Submission
3.	Capecitabine 500mg	44 Patients	CANCER PATIENTS 1. Ca.Breast 2. Ca.Rectum 3. Ca. Colon	EU Submission
4.	Capecitabine 500mg	54 Patients	CANCER PATIENTS 1. Ca.Breast 2. Ca.Rectum 3. Ca. Colon	US FDA Submission
5.	Temozolomide 250 Mg	24 Patients	HIGH GRADE GLIOMA	US FDA Submission
6	Omega-3 Acid Ethyl Esters	36 Patients	HYPERTRIGLYCERIDEMIA	DCGI Submission
Phase III Trial				
6.	Moist Exposed Burn Ointment (MEBO)	120 Patients	MILD THERMAL BURN INJURIES	DCGI Submission

MOLECULES EXPERIENCE

Science with Ethics

S.NO	MOLECULES	NO. OF SUBJECTS	INDICATIONS
1.	Temozolomide 250 mg	12 Patients	GLIOBLASTOMAMULTIFORME or REFRACTORY ANAPLASTIC ASTROCYTOMA
2.	Capecitabine 500mg (Fast condition)	18 Patients	CANCER PATIENTS Ca. Breast Ca. Rectum Ca. Colon
3.	Capecitabine 500mg (Fed condition)	18 Patients	CANCER PATIENTS Ca. Breast Ca. Rectum Ca. Colon
4.	GOODLYFE in control blood sugar	10 Adult Patients	TYPE 2 DIABETES
5.	GOODLYFE in controlling blood pressure	10 Adult Patients	MILDLY ELEVATED BLOOD PRESSURE
6.	Leuprolide Acetate 7.5 mg	60 Patients	PROSTATIC CARCINOMA
Bio Marker studies			
7.	Collection of specimen (serum)	200 subjects	TYPE I DIABETES MELLITUS UNDER FASTING/FED CONDITIONS
		200 Patients	METASTATIC BREASTCANCER STAGE IV
		100 Patients	METASTATIC BREAST CANCER STAGE IV

MOLECULES EXPERIENCE

Science with Ethics

Proof of Concept Study			
S.No	**MOLECULES**	**NO. OF SUBJECTS**	**INDICATIONS**
1.	**Vida-Defense 500mg Capsule**	**100 Patients**	**Cancer patients receiving standard chemo/radiotherapy**

Ongoing Studies			
S.No	**MOLECULES**	**NO. OF SUBJECTS**	**INDICATIONS**
1.	**Bortezomib Powder for Solution For Injection 3.5 mg/vial**	**40 Patients**	**Multiple Myeloma**
2.	**Leuprolide Acetate 7.5 mg**	**12 Patients**	**Prostatic Carcinoma**
3.	**Doxorubicin Hydrochloride Liposome Injection 2mg/ml (50mg/m^2 dose)**	**54 Patients**	**Metastatic Breast Cancer/Advanced Ovarian Cancer**

CONTACT DETAILS

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Corporate Facility:

Micro Therapeutic Research Labs Pvt. Ltd.
Rajam Bhavanam, Door No. 6, Kamarajar Salai,
Selaiyur, East Tambaram, Chennai- 600059,
Tamilnadu, India
Tel No: (+91) 9444384232 /
(+91-44)22390070/71
Fax No: (+91 44) 22390069

Chrompet Facility:

Micro Therapeutic Research Labs Pvt. Ltd.
Plot No. 46 (Part), Rengasamy Street,
Chrompet , Chennai-600044,
Tamilnadu, India

Tel No. (+91) 9500152780 /
(+91)9940502533

Preclinical & Biosimilars Facility:

Micro Therapeutic Research Labs Pvt. Ltd.
Door No. 50&51, Balaji Nagar, 3rd Street,
Padi, Chennai- 600050
Tamilnadu, India

Tel No. (+91 44) 26541195

Coimbatore Facility:

Micro Therapeutic Research Labs Pvt. Ltd.
Door No.29 A, Krishna Madura Vanam,
Vellakinar Pirivu, Thudiyalur,
Coimbatore – 641029,
Tamilnadu, India.

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Thank You