MELIOR

LIFE | SCIENCES

ALWAYS AIMING FOR BETTER

ABOUT US

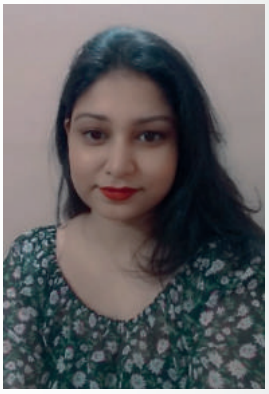
Melior Life Sciences is a full-service clinical research organization dedicated to innovation in medical therapies leading to better and safer treatment modalities.

We are a reliable and enterprising entity offering services such as **Medical Writing, Medical Monitoring, Biostatistics, Protocol Development, Data Management, Evidence Evaluation, electronic common technical document (eCTD) Modules, Safety & Pharmacovigilance and Regulatory.** Our understanding of the intricacies and nitty-gritties of the local and international regulations combined with our experts' depth of knowledge ensures the timely delivery of the services with the highest standards of quality.

OUR TEAM

CEO
JATINDER MITTAL

DIRECTOR
ANKIT MITTAL



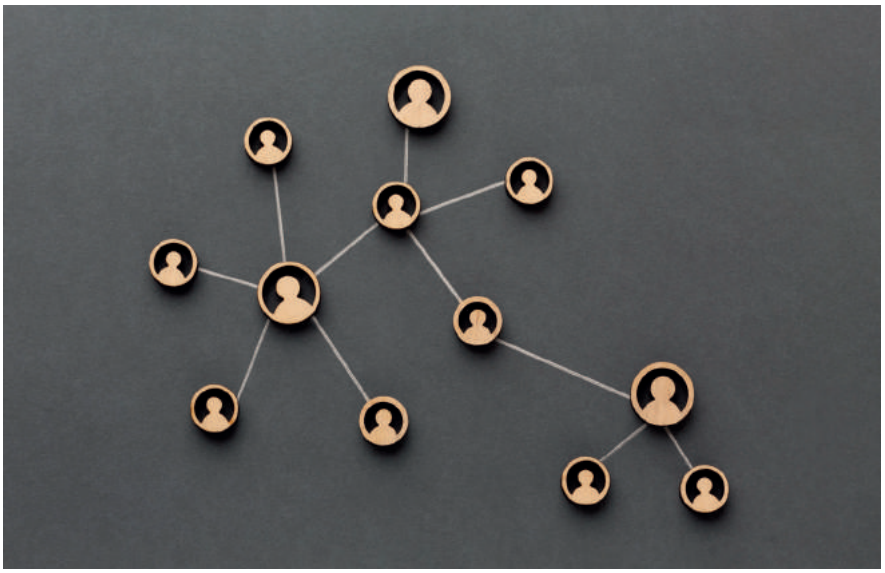
MEDICAL WRITER HEAD
SHALU CHAUHAN

OUR TEAM

Dr. Kunal Yadav
is a Transplant Surgeon, specializing in kidney, liver and pancreas transplantation.
He is currently working as Assistant Professor of Surgery at University of Toledo, USA

Dr. Sunil Jeph
is a board-certified radiologist and Assistant Professor of Radiology at
Penn State Health Milton S. Hershey Medical Center and Penn State College of Medicine.

Dr. Paras Singhal
is a Urologist and Kidney Transplant Surgeon. He also did a 1 year Prostate Cancer Research Fellowship from Weill Cornell and Mount Sinai Hospitals at New York, US.



Dr. Gourav Gupta
did MD-Psychiatry from one of the most prestigious institutes in India,
Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh

Dr. Nitin Mishra
is a consultant interventional radiologist

Dr. Isha Wadhawan
is one of the most esteemed Gynaecologist, Obstetrician and Laparoscopic Surgeon (Obs & Gyn) in Delhi

Dr. Anand Venkatraman
is a Neurologist specializing in Neuroendovascular surgery and Neurocritical care.

OUR SERVICES

01 CLINICAL RESEARCH SERVICES

Melior Lifesciences offers a robust suite of services for your Phase I-IV clinical trials, registries, and other clinical research initiatives.

Statistical Design and Analysis

- Protocol design and pre-study feasibility
- Statistical analysis plan
- Central statistical monitoring
- Data and Safety Monitoring Board support
- Reporting and manuscript preparation

Protocol Development and Data Management

- Protocol document review for consistency, completeness and clarity
- Creation of electronic Case Report Forms (eCRFs)
- Deployment of electronic data capture system
- Site support, data cleaning and quality control processes to ensure data integrity

Investigator, Site and Patient Services

- Site identification, recruiting, selection, activation, and monitoring
- Site regulatory compliance monitoring
- Patient recruitment, screening, registration, blinding and management

- Electronic patient reported outcomes (ePRO) data collection and support services
- Site auditing to ensure study progress

Safety and Pharmacovigilance Services

- Safety monitoring
- Adverse Event (AE) and Serious Adverse Event (SAE) reporting on site and country levels
- Case processing
- SAE narrative writing and submissions
- Aggregate safety reporting, event trend and signal detection services
- Adverse event coding according to Medical Dictionary for Regulatory Activities (MedDRA)

Regulatory Affairs Support

- Country and site-level regulatory authority applications
- Investigational New Drug (IND) and Investigational Device Exemption (IDE) submissions
- Maintenance of Biologics License Applications (BLAs), IND applications and Trial Master Files (TMFs)
- Medical writing and Clinical Study Report compilation

Information Technology

- Suite of clinical data collection, management and analysis tools
- Electronic data capture (EDC) of case report forms and other study data
- Patient randomization and blinding
- Inventory management/tracking of specimens and shipments
- Pharmacovigilance monitoring and management
- Electronic patient reported outcomes (ePRO)

Medical Writing

- Protocols for both interventional and non-interventional trials or investigations
- Informed consent forms
- Data management plans, statistical analysis plans, monitoring plans, site operational manuals, etc...
- Clinical study reports: interventional and non-interventional trials
- Product or disease registries
- Manuscripts, posters, and presentations for the trial result publication

Quality Assurance

- Auditing of study data, sites, laboratories, 3rd party vendors, and Contract Research Organizations (CROs) to ensure operations follow established procedures

02 BIOSTATISTICS

Collecting, analyzing and interpreting data are essential components of biomedical research.

Although applying statistics has become very easy with the development of good computer softwares, a good understanding of biostatistics is important for two reasons: first, to choose the right test for the computer to apply and second, to evaluate the analysis of review and for interpretation of other's research.

The importance of biostatistics in every clinical trial is obvious. Statistical skills are required at study design and analysis of the clinical trial. A good statistical approach is crucial to derive the high-quality data required to analyze the end points of any interventional study and goals of any observational study.

03 PROTOCOL DEVELOPMENT

The first step for every study is the development of a protocol that is scientifically sound and complete to meet the objectives. We assist you in that, laying the foundation required for the success of any clinical study.

We help in developing electronic case report form (eCRF) and deployment of

electronic data capture (EDC) system. In addition, we provide the site support and quality control processes required to clean the crucial data and maintain its integrity Writing the research protocol is the most challenging and difficult task as research is usually done in new areas and to know the previously unknown. We understand the necessary steps and guidelines required for producing a standard research protocol. It essentially describes the eligibility of the participants, length of the study, and involved medications and tests. The importance of the quality for writing a protocol is obvious as it not only determines the success or failure of the project but also may determine initially the approval of the project and grant of funds to carry out the project itself.

04 DATA MANAGEMENT

We provide comprehensive solutions for your data management needs. Data management is crucial component for any study. From data collection to data validation and data validation to produce reliable, consistent and high quality data ready for statistical analysis in secured manner requires robust data management framework. Our data managers with the help of experienced and competent statisticians provide everything that is required for the whole process of data management.

As part of data management we provide the following services:

1. eCRF design
2. Edit check validation
3. Data export for analysis/monitoring/data cleaning
4. Data reports in regulatory formats

05 SAFETY AND PHARMACOVIGILANCE SERVICES

Safety issues can vary depending upon the disease type and severity, requiring expertise across various therapeutic areas. We can confidently assess and address safety challenges. We are committed to patient safety and overall positive outcomes of modern medicine.

Pharmacovigilance involves the processes of monitoring and evaluating adverse drug reactions, and it is a key component of effective drug regulations and patient treatment. A high level of expertise is required to rapidly detect drug risks and to devise a successful risk management plan and safeguard the inappropriate removal of

the drug from the market. Pharmacovigilance is an important and integral part of clinical research. It is growing rapidly in many countries and, hence, demanding a robust and effective system for better safety and monitoring of drugs.

06 MEDICAL MONITORING

Our medical monitoring expertise across various therapeutic areas ensures that studies are conducted appropriately and in compliance to regulatory requirements and ICH GCP guidelines. Medical support throughout the study supports the sites to conduct the study without any doubt and confusion, and data review ensures the quality and integrity of the clinical data and, hence

We provide end-to end monitoring services – reviewing the protocol, informed consent documents, planning documents and other pertinent study documents. It also includes reviewing hospital medical records; issue queries; checking master files; attending study teleconferences; assisting in the preparation of regulatory submission dossier, site evaluation and selection, clinical sites with IRB submission etc. Different skills are required for different tasks, so the monitor has to play different roles. We assure you to provide the best monitoring services and help in the successful conduct of your study.

07 EVIDENCE EVALUATION

We provide Evidence Evaluation services from phase 1 to phase 4 of the studies, and solutions based on that can help in devising risk management strategy, regulatory compliance, and outcomes research and meeting market-specific objectives.

08 MEDICAL WRITING

Medical writing involves writing different types of scientific documents. Medical writers understand how the scientific information should be presented to suit the target audience: patients, public, physicians, or regulators. They are well versed with the medical concepts and terminologies, relevant guidelines, and structure and content of a specific document.

We can help the following list of documents:

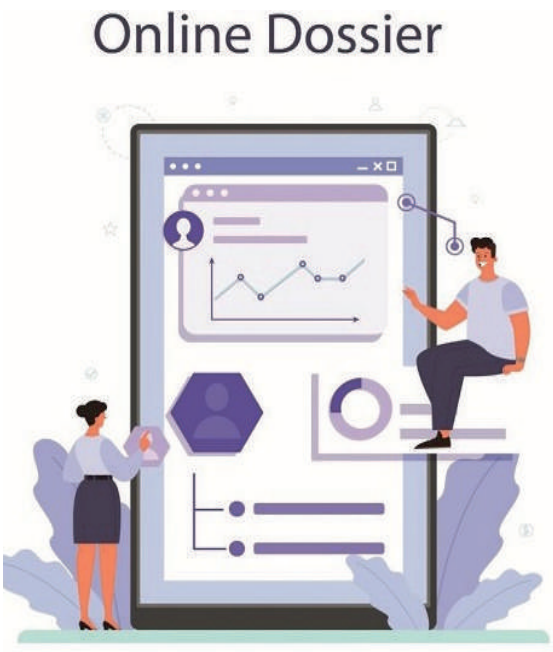
1. Protocols
2. Information brochures
3. Informed consent documents
4. Clinical study reports
5. Subject narratives
6. Conference slide kits
7. Standard response letters and frequently asked questions
8. Manuscripts
9. Posters
10. Continuing medical education slide kits
11. Patient information leaflets
12. Electronic common technical document modules

09 eCTD MODULES

The eCTD is the standard format for submitting applications, amendments, supplements, and reports to regulatory agency in many countries.

Electronic submissions of standardized study data will be required for the following submission types:

1. Certain investigational new drug applications (INDs)
2. New drug applications (NDAs)
3. Abbreviated new drug applications (ANDAs)
4. Certain biologics license applications (BLAs)



Note: This requirement also includes all subsequent submissions, including amendments, supplements and reports to one of the submission types identified above.

10 REGULATORY SERVICES

We understand the regulatory landscape and can help you devise a strategy to fulfill regulatory obligations. Regulatory framework is becoming more and more stringent and complex as far as pharmaceuticals for human use are concerned.

From regulatory viewpoint, we can help you in the following areas:

1.Framing responses to queries from regulatory agencies
2. Scientific input in interactions with regulatory agencies
3. Dossier development and management for the products
4. Identification of Medicinal Products/Extended EudraVigilance medicinal product dictionary

THERAPEUTIC AREAS OF CLINICAL RESEARCH

Our expertise in many therapeutic areas of clinical research ensures that we move your molecule forward, through our Clinical research services. As a full development program or a stand-alone service, we apply our expertise in therapeutic areas in clinical research to everything we do. We will help seamlessly transition your molecule through the phases of development in any of our therapeutic specialties, helping you get your drug to market faster.

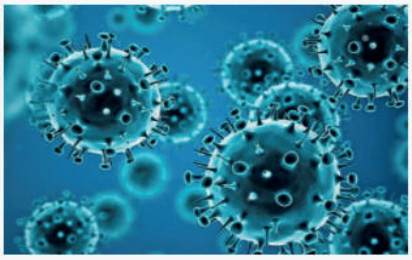
Gastroenterology

Orthopedics

Psychiatry

Cardiology

Neurology



Covid

OUR VISION

Our vision is to be an unmatched leader in providing safety and development solutions for the pharmaceutical industry.

OUR MISSION

We as a team are dedicated to provide quality of work to meet the highest standards. In doing so, we aim to provide the best support and the best solutions for the pharmaceutical industry, resulting in safer and better therapeutic modalities for the service of mankind.

CONTACT US

ADDRESS: B-1034, Greenfield Colony,
Faridabad, Haryana, 121003
MOBILE: (+91) 9311053006, 9311053007
MAIL: info@meliorlifesciences.com