Medical Innovation with Ethics

Empowering Advances in Healthcare with Ethical Clinical Research

Methics Clinical

Transforming Clinical Trials with Ethics and Expertise

At Methics, we believe that medical advancements and ethical principles go hand in hand. Our mission is to push the boundaries of what’s possible in healthcare by conducting clinical trials that are safe, effective, and respectful of human rights.

We leverage the latest technology and innovative methods to design and execute clinical trials that deliver meaningful results.

We are a boutique clinical research organization that is dedicated to providing a full range of clinical trial services. Our team of experienced professionals and global partners work together to deliver innovative and ethical solutions for every step of the clinical trial process.

End-to-End Clinical Research Solutions

While each of our departments' services can bring you value on their own, you can also benefit from end-to-end clinical trial solutions that provide support from ideation all the way to successful market entry. Enjoy the ease of working with several departments all housed under one roof that work in cohesion to quickly address your organization's specific needs.

Methics is a well-structured organization with deep clinical research experience team, which means we have the flexibility to provide you with tailored solutions for all the clinical research challenges you might face. Our experienced professionals have the ability to work together within limited timeframes and provide you with the rapid set-up times to accelerate your product's development life cycle and efficiently meet your clinical goals.

Full Flexibility through 100% Customization

We are a full service CRO. We take this literally – whether you choose all or some of our service functions. Our service is always tailored to your needs and reflected in everything we do.

Clinical Operations

Project Management

Medical Monitoring/ Safety Management

Medical Writing

Regulatory Affairs

Quality Assurance

Data Management

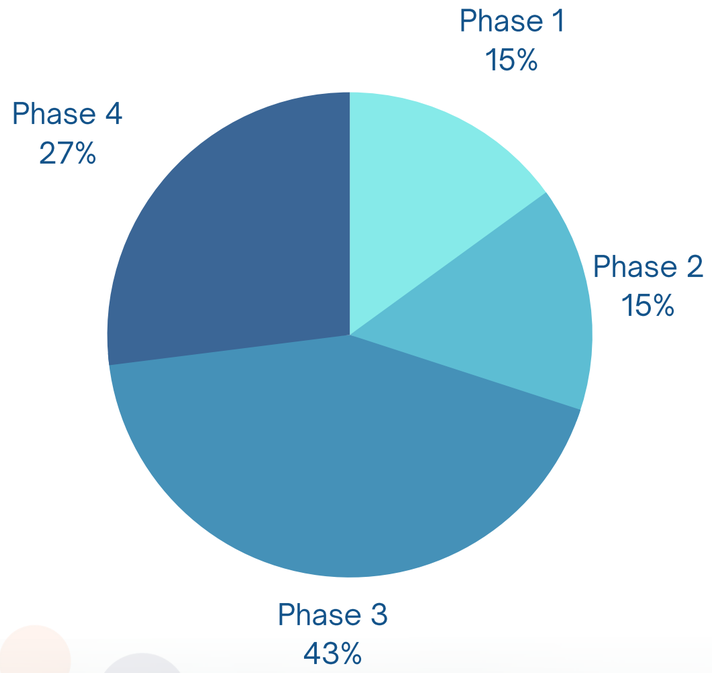
Bio-Statistics

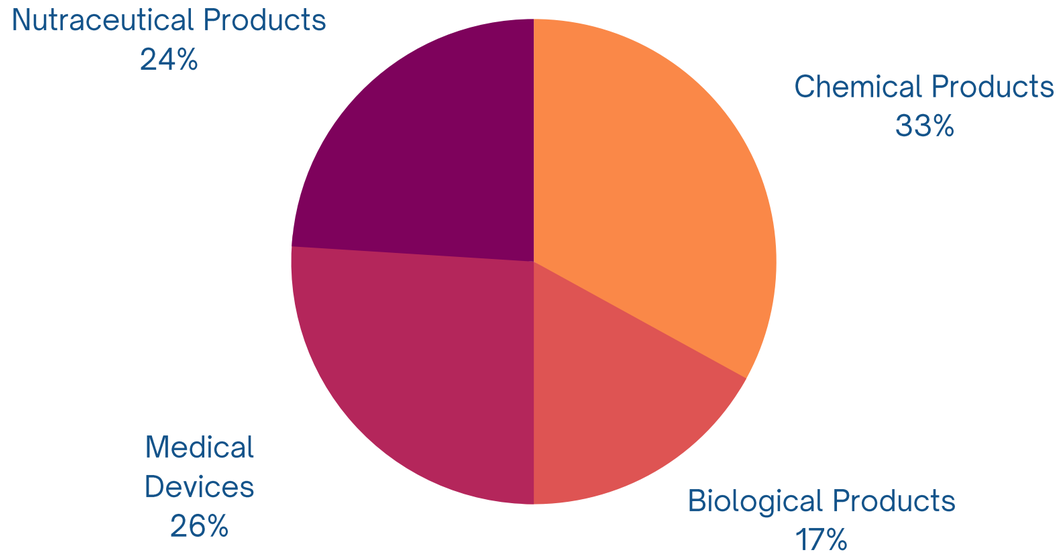
Reliable, Faster & Innovative Team that sets us Apart

- Well established and stable team
- Highly skilled and experienced
- Pro-active and open communication
- Ownership over the responsibilities
- Implementing smart and practical solutions
- Measurable performance through Milestone
- Quick responsiveness and reaction time

Clinical Team Experience

With 100+ Clinical Trial experience in various Therapeutics





Wide Range of Therapeutic Areas experiences

- Cardiovascular
- Ophthalmology
- Oncology
- Respiratory
- Gastroenterology
- Infectious disease
- Psychiatric
- Dermatology
- Nephrology
- Orthopedic
- Vaccine Development

Clinical Operations

- Feasibility studies
- Site Selection and Initiation
- Monitoring- Onsite/Remote/Centralize
- Close out
- Patient Recruitment support
- Site Management

Navigating the Complexities of Clinical Operations with Ease

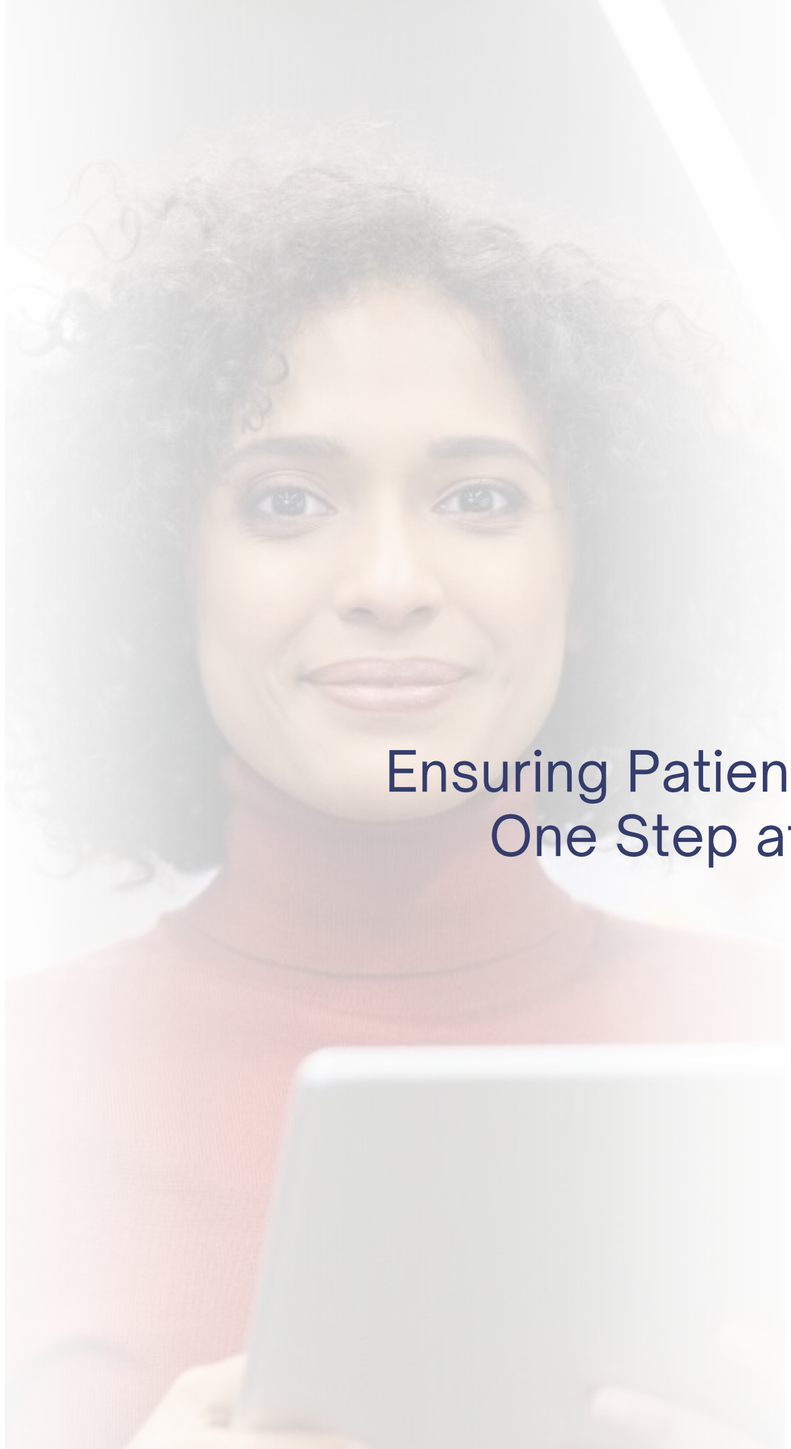
Project Management

- Scientific Leadership
- Project planning, execution and monitoring
- Provide project progress report
- Risk Management
- Stake holder and vendor management
- Incorporate quality best practices
- Put Strategic plan into practice
- Management of regulatory and compliance strategies

Turning complex projects into simple solutions

Medical Monitoring

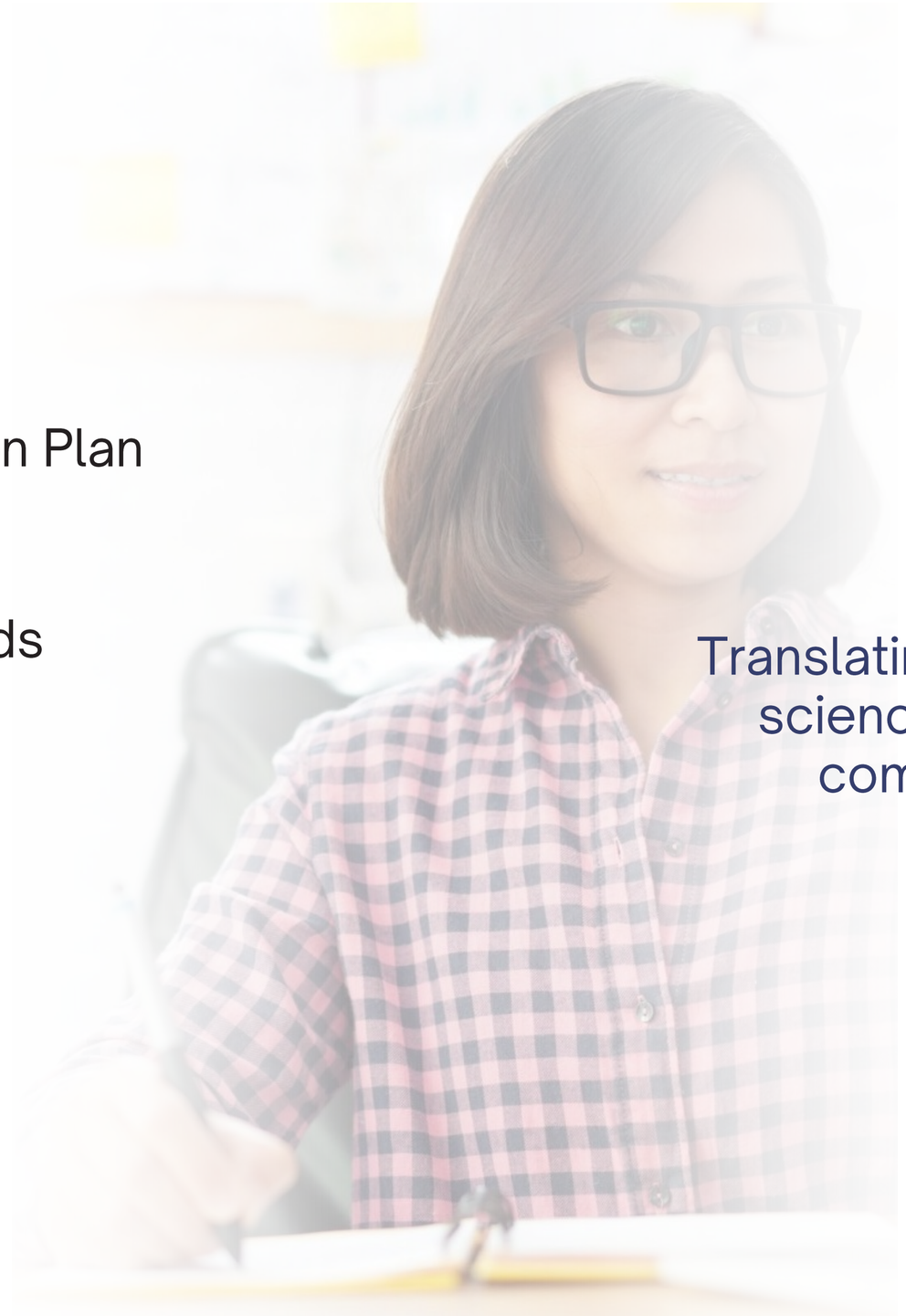
- Medical inputs in protocol development
- Safety Management Plan
- Medical Monitoring Plan
- Clinical case review
- Medical and safety line listing review and discussion
- Medical coding review
- SAE/SADE/Pregnancy cases review



Ensuring Patient Safety,
One Step at a Time.

Medical Writing

- Clinical Study Protocol /Investigation Plan
- Investigator’s brochures (IB)
- Consent documents
- Patient scales and patient diary cards
- Clinical Study/Investigation Report
- Manuscript writing
- Scientific document



Translating complex science into clear communication

Regulatory Affairs

- Clinical Regulatory Strategy Development
- Clinical & Non-Clinical overview (2.4 & 2.5) Writing
- Expert statement clinical and non clinical signature of expert
- Drafting SmPC, PILs, PIs, Medical Guide
- Environmental Risk Assessment
- Permitted daily Exposure
- Module 4 writing and review cover the Preclinical activity
- Dossier compilation & Review
- Regulatory writing and reporting

Your partner in regulatory compliance and success.

Quality Assurance

- QMS Setup
- Vendor qualification
- Computer System Validation (CSV)
- Pre- Audit/ Inspection readiness
- Change Management
- Deviation Management
- GxP/Compliance Audits

Quality as a principal guidance for all Research

Data Management

- EDC Selection and End-User training
- Data Management Plan
- Database design, development and maintenance
- Data cleaning and query management
- Medical coding (WHO-DD and MedDRA)
- SAE/SADE and third party data Reconciliation
- Data base lock, transfer and archival

Unlocking the Power of
Your Data with
Precision and Quality

Biostatistics

- Study design and protocol development
- Sample size calculation
- Randomization schemes
- Statistical Analysis Plan
- Statistical Analysis and report
- Integrated safety and efficacy analysis
- Data Monitoring Committee Services
- SDTM and ADaM data set preparation

Redefining the future of healthcare through data analysis.

Team experience in e-Tools

- EDC
- IWRS/RTSM
- CTMS
- eTMF
- rSDV
- ePRO
- eCOA
- eConsent

Medical device & IVD Solution

- ISO 13485 Quality Management System setup and implementation
- Product Registration and Market Authorization
- Import and Export compliance for Medical Devices & IVDs
- CE Marking documentation in accordance with MDR / IVDR
- Medical Device Single Audit Program (MDSAP) preparation
- 510(k) application preparation and submission (FDA)
- Clinical Evaluation Report (CER) writing
- Clinical investigation planning and management
- Post-Market Clinical Follow-Up (PMCF)

We provide comprehensive support across the entire lifecycle of Medical Devices (MD) and Vitro Diagnostics (IVDs), ensuring compliance, efficiency, and market success.

Clinical Project Workflow

Quality You Can Rely Upon

Well-established Quality Management system

In-House Designed SOPs

System Audit by Sponsors

FDA / EMA Acceptable Data

Why Choose Methics?

Ethical Approch

We are guided by a strong commitment to medical ethics and human rights, and we work tirelessly to ensure that all of our clinical trials are conducted with the utmost integrity

Cutting-Edge Technology

We use the latest technology and innovative methods to design and execute clinical trials that deliver meaningful results.

Experience

Our team of experts has extensive experience in the design, execution, and management of clinical trials

Patient Care

Our participants are at the heart of everything we do, and we are committed to providing them with the best possible care and support throughout the clinical trial process.

Whatever your concern, we are here to help!

Contact Us

bd@methicsclinical.com

www.methicsclinical.com

S-05 & S-06, Second Floor, Kalaji Business Centre,
Near Saurashtra Kadva Patidar Vadi, Dharampur Chokdi,
Abrama, Valsad – 396002, Gujarat, India.

Methics
Clinical