



# Medical Innovation with Ethics

Empowering Advances in Healthcare  
with Ethical Clinical Research





# 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.



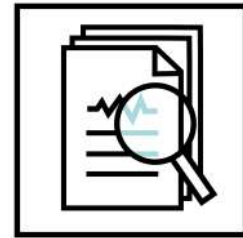


# Full Flexibility through 100% Customization

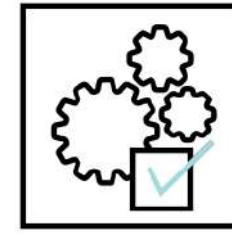
We are a full service CRO. We take this literally – whether you choose all or some of our service functions. Our service is always tailored to your needs and reflected in everything we do.



**Clinical  
Operations**



**Medical  
Monitoring/  
Safety  
Management**



**Regulatory  
Affairs**



**Data  
Management**



**Quality  
Assurance**



**Bio-  
Statistics**



**Project  
Management**



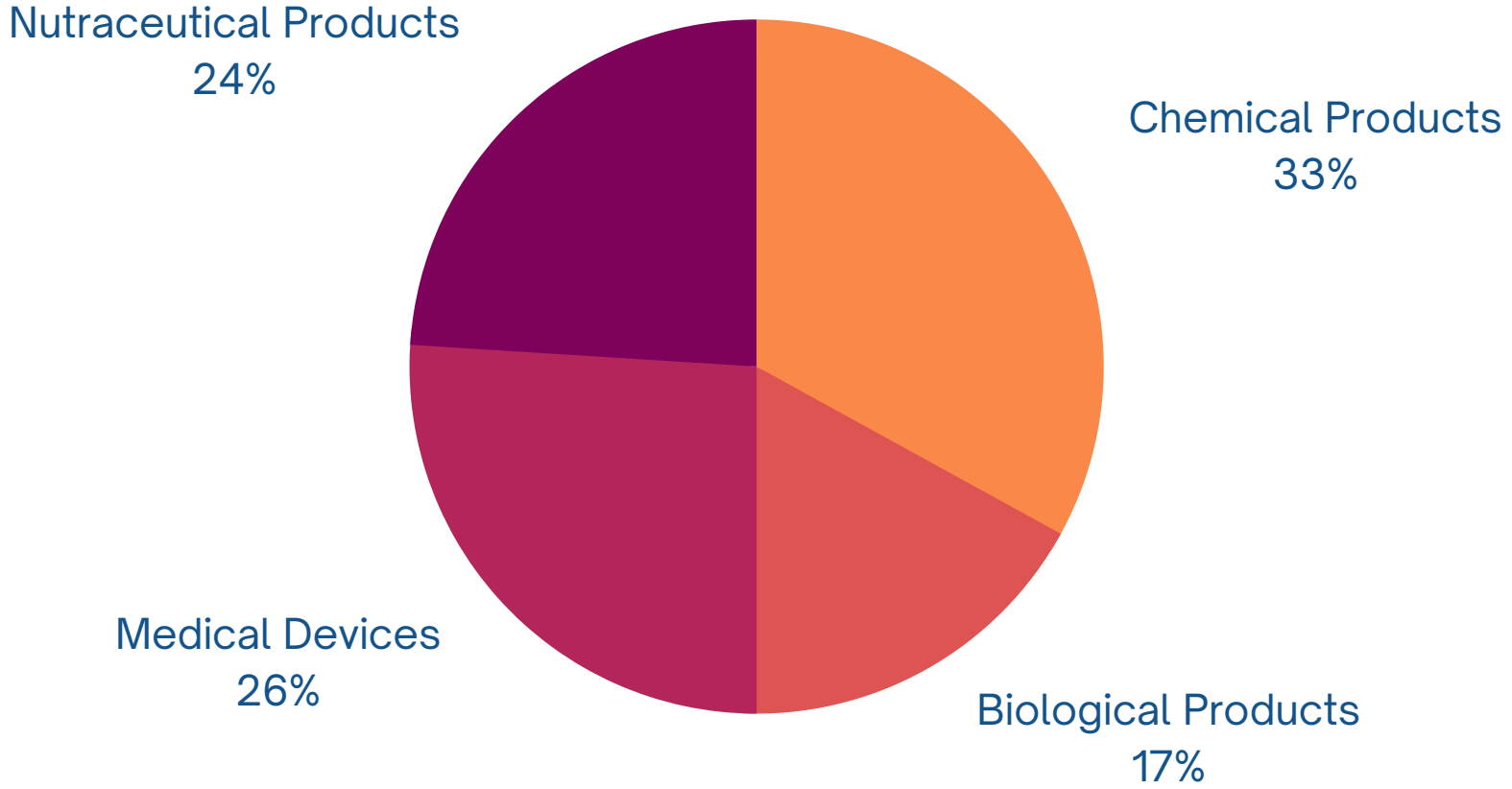
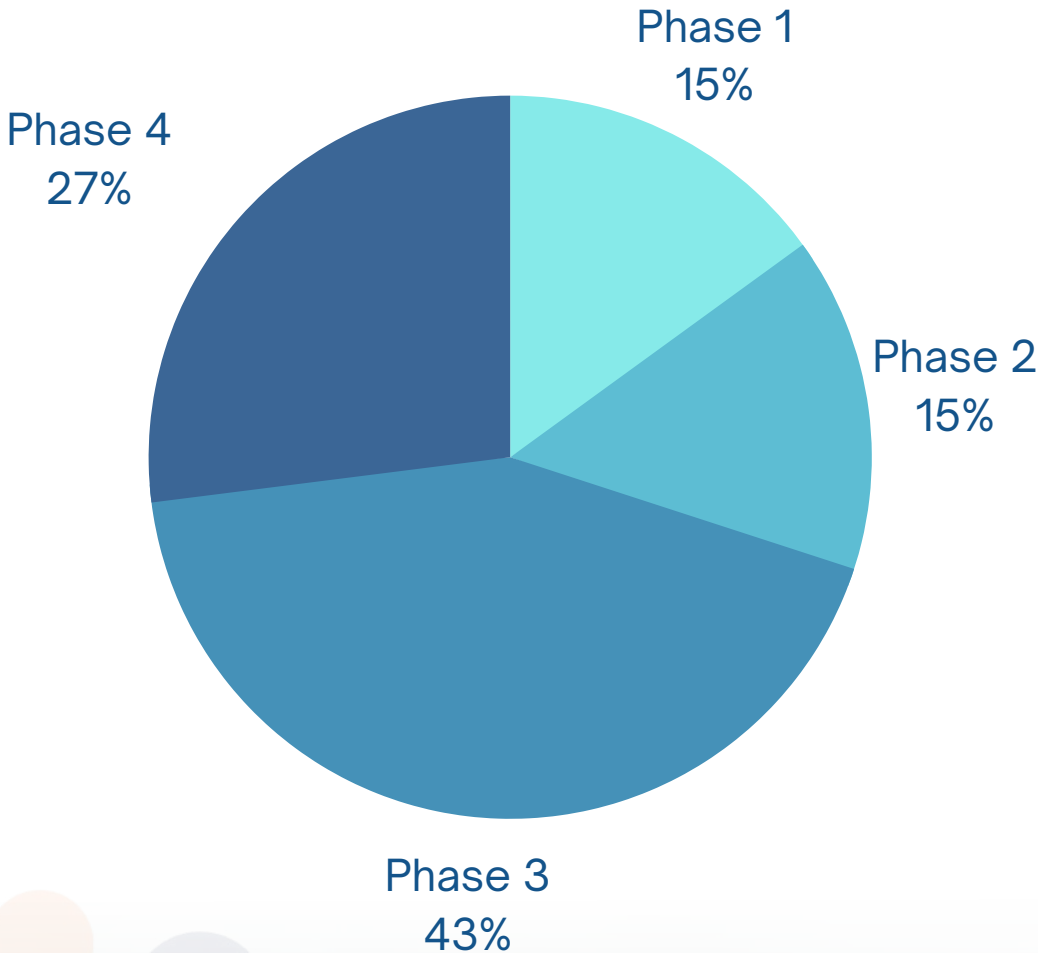
**Medical  
Writing**

# 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





# Wide Range of Therapeutic Areas experiences

- Cardiovascular
- Ophthalmology
- Oncology
- Respiratory
- Gastroenterology
- Infectious disease
- Psychiatric
- Dermatology
- Nephrology
- Orthopaedic
- 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

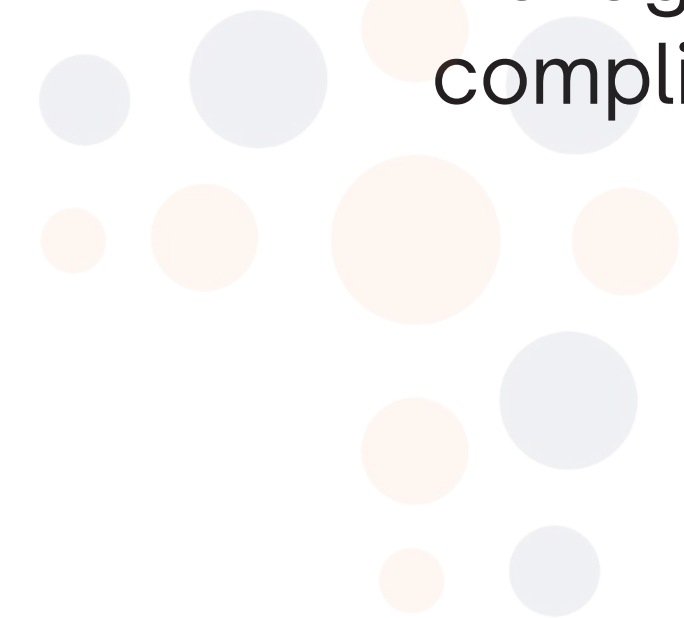




# Project Management

- 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

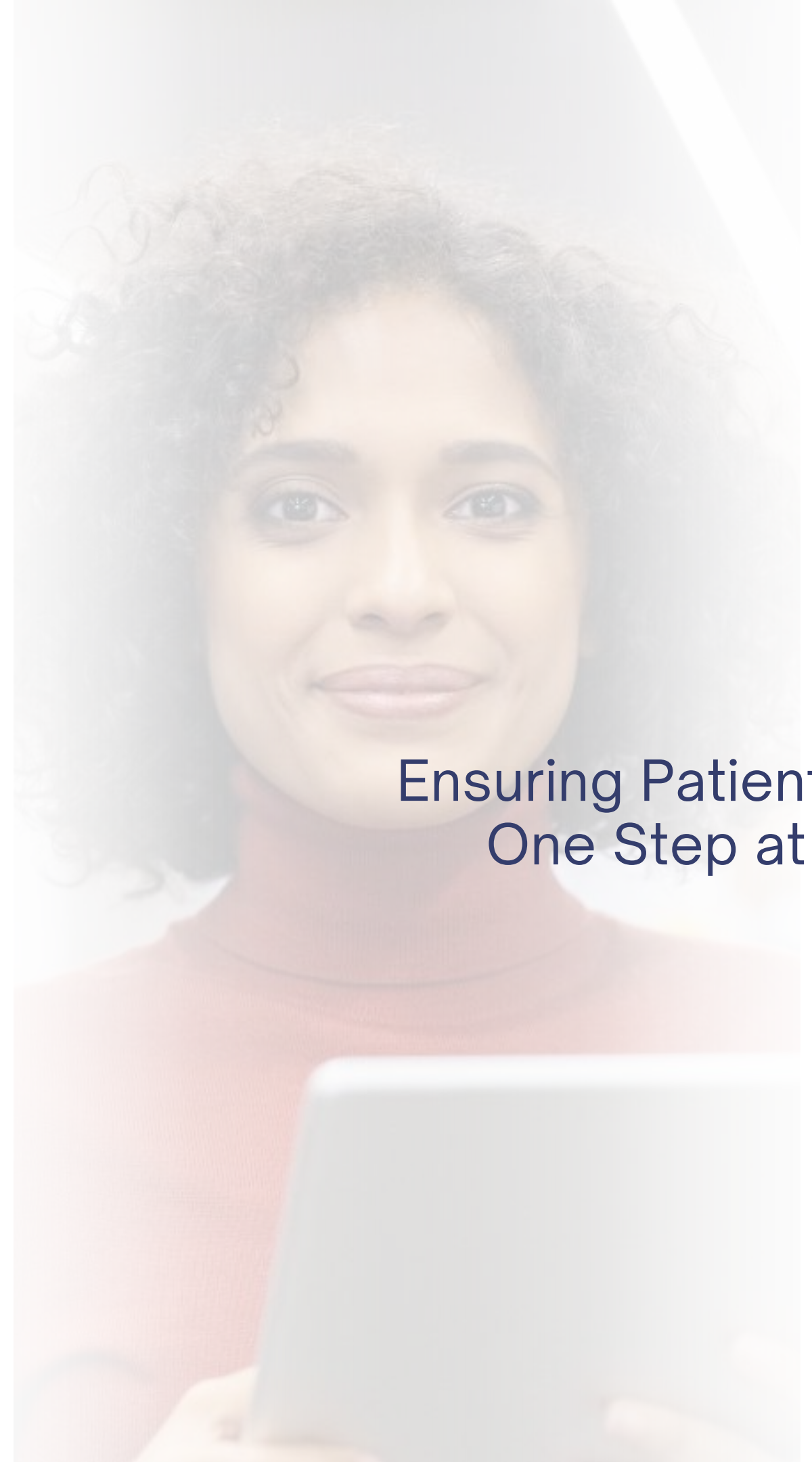
Turning complex projects into simple solutions



# 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

- Regulatory Strategy development
- Pre-Submission Preparations
- Review & Submit Regulatory dossiers
- IRB, Local and Central EC Submissions
- 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

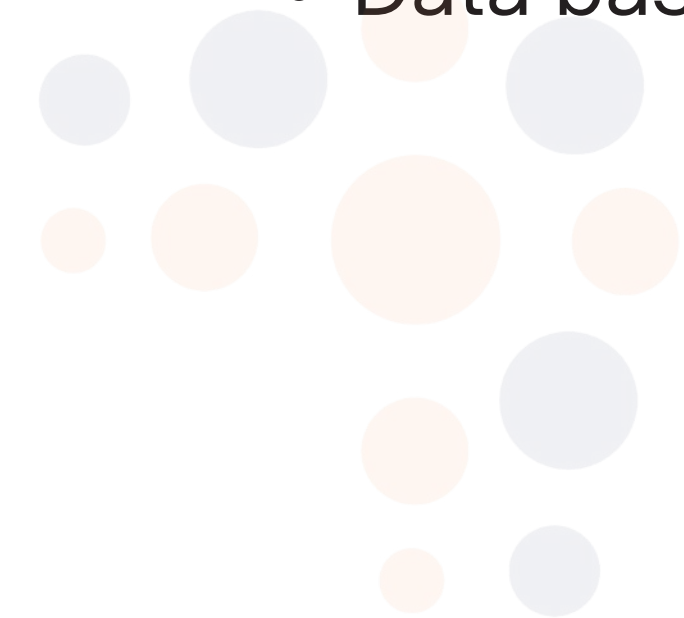
Quality as a principal  
guidance for all  
Research



# 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





# 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?

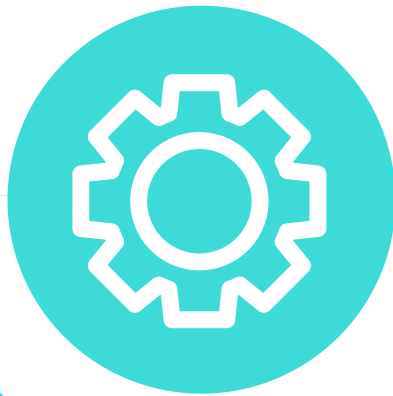
## Ethical Approach



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

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

## Cutting-Edge Technology



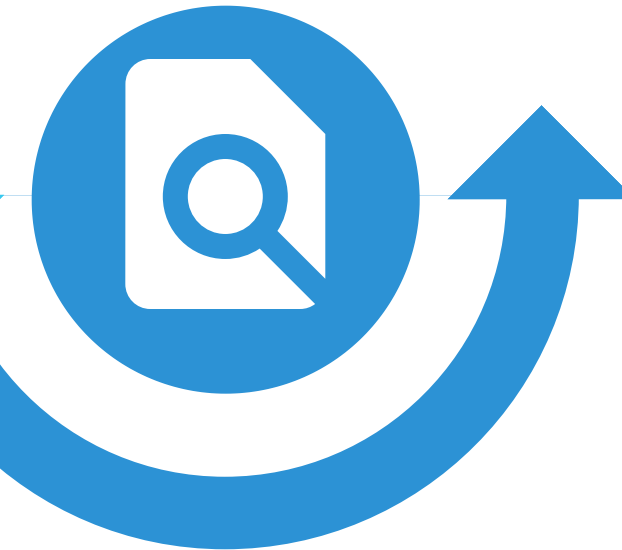
## Experience



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

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.

## Patient Care



# Whatever your concern, we are here to help!

## Contact Us

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**Methics**  
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