Your Site. Our Eyes.

We focus on **executing your study** and **achieving compliance** so you can **earn regulatory approval** and **bring your product to market faster**.



IMARC is a leading clinical research organization that ensures compliance for studies of medical devices and biotechnologies.

We have studied clinical research and regulatory compliance issues since 1999, and none of our sites or sponsors have received a single warning letter in that time.

Now, we invite you to study us...

YOUR PARTNERS *in Compliance*

Regulatory approval is your ultimate goal, and we care about achieving it as much as you do. Our team is committed to ensuring compliance at every stage so your team can reach the finish line faster.



OUR SERVICES

IMARC enhances your clinical trial at every stage, from planning to closeout.

Though our team is capable of stepping in at any point in your clinical research trial, we offer the best value when we are involved from start to finish. This way we can offer comprehensive, risk-based planning, consulting and oversight from all angles, ensuring your data and overall study integrity is beyond reproach.

Whether you represent a research site, sponsor or CRO, our experienced team will ensure your study meets all relevant requirements for human subject protection and regulatory standards while using your time and resources as efficiently as possible.

> **imatc** We'll EARN YOUR APPROVAL.

LEARN MORE ABOUT OUR SERVICES



MONITORING

Our approach to monitoring goes beyond following a checklist. Our team brings critical thinking and practical experience to your project to develop and implement the most effective risk-based strategies.

PROJECT MANAGEMENT

Our team brings exceptional leadership and measurable process improvements to any trial, based on nearly two decades of experience in the field. Our project managers proactively address issues and communicate with vendors, keeping you updated on the progress of your study. Your study will avoid common pitfalls, progress faster and more efficiently, and include the IMARC approach to ensure study compliance.



AUDITING

Our auditing programs provide an efficient process-level assessment of Good Clinical Practice compliance at research sites, sponsors, Institutional Review Boards, and vendors. We conduct audits globally against applicable study and regulatory requirements, and we will assess inspection-readiness while preparing your team.

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TRAINING

A well-trained staff is key to the success and integrity of your clinical study. IMARC University offers comprehensive training that can be customized to meet the needs of your team or individual staff members. Our training options include cost-effective in-person training, teleconferencing and convenient online courses.



SAFETY MANAGEMENT: DSMB AND CEC

The Data Safety Monitoring Board and Clinical Events Committee provide added layers of objective oversight and credibility to your study. IMARC has established an extensive network of physicians and specialists to offer comprehensive safety monitoring so you can be confident in your study results. IMARC will manage all administration details, from assembling the board, to arranging and documenting meetings, to providing Sunshine Act financial reporting.



CONSULTING

Cumbersome, absent or unfocused processes can overcomplicate your study, or worse, set you up for noncompliance. Our consultants have the experience to evaluate clinical department weaknesses and address your needs, whether you need a full quality system overhaul or simply help re-strategizing.

SITE SUPPORT

Let IMARC handle the paperwork, data collection, data entry, and other site responsibilities so your sites can prioritize their time toward recruitment and retention. We offer comprehensive site support to accomplish enrollment goals ahead of schedule, provide clean data on time, and enhance your team's efficiency.



OUR TEAM

Our team represents a broad range of medical research backgrounds, enabling us to provide expertise for medical device, biotech and drug studies. We work with sponsors and sponsor investigators in a variety of therapeutic areas so we can adapt our approach to your needs.

Here's a look at some of our specialty areas.

TECHNOLOGICAL EXPERTISE

- Autologous Muscle Derived Cells
- Combination Products
- Chemotherapeutic Agents
- Drug-Eluting, Balloon-Expandable and Self-Expanding Stents
- Endovascular Grafts for Treatment of Aneurysms
- Inferior Vena Cava (IVC) Filters
- Atrial Appendage Devices
- Balloon Catheters
- Wound Matrices
- Defibrillation Devices
- Hip and Knee Replacement Systems
- Functional Electrical Stimulation Systems

THERAPEUTIC EXPERIENCE

- Cardiovascular
- Peripheral Vascular
- Neurovascular
- Orthopedics
- In Vitro Diagnostics
- Wound Care
- Pediatrics
- Gastrointestinal
- Genitourinary
- Women's Health
- Oncology
- Ophthalmic
- Rehabilitation/Pain
- Emergency Medicine

Begin your next project confidently with a compliance-minded CRO you can trust. Contact us today.



22560 Lunn Road, Strongsville, Ohio 44149 • Tel: 440.801.1540 imarcresearch.com • info@imarcresearch.com