IMARC Research, Inc.

EXECUTIVE SUMMARY

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WE'LL EARN YOUR APPROVAL.

WHO WE ARE

IMARC is a ISO 9001:2015 certified, global, full-service clinical research organization that ensures compliance for studies of medical devices and biotechnologies. Founded in 1999 by Sandra Maddock, a nurse and former research coordinator with a passion for protecting patients, our team is committed to supporting you at every stage in your trial so your team can reach the finish line faster.

We use standardized processes and best practices we have perfected over more than two decades to protect the integrity of your study and enhance your team's efficiency.

Our company is headquartered in Strongsville, Ohio, just minutes from Cleveland Hopkins International Airport, with a satellite office in Minnetonka, Minnesota, providing both our clients and staff with easy travel access.

THE RIGHT SIZE CRO

When searching for a contract research organization (CRO), bigger isn't always better. Some companies choose a large CRO only to find their main point of contact was inaccessible when they needed them or their study team turned over (maybe more than once), which caused them to experience delays. Maybe the organization allowed the trial to go significantly over budget, or added layers of complexity to the trial conduct that weren't actually necessary.

The right-size CRO will have several qualities that lead your trial to success, including strong management support, a medical device focus, a flexible approach, study team stability and more. As a medium-sized CRO with global partnerships and specific expertise in medical device trials, IMARC Research is the right size to support your clinical study support needs.

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OUR MEDICAL DEVICE EXPERTISE

Sponsor-Funded Research

- Pilot/ Feasibility
- IDEs
- 510(k)s
- Post approval studies
- 522-ordered studies

Investigator-Initiated IDEs

- Site perspective
- Sponsor perspective

Study Experience

- Cardiovascular
  - Interventional
  - Peripheral
  - Vascular
- Orthopedics
- In Vitro Diagnostics (IVDs)
- Neurological
- Wound Care
- Pediatrics
- And more...

OUR SERVICES CAN HELP YOU:

- Manage complex trials
- Address top FDA failures
- Secure FDA approval; our sites have never received an FDA warning letter
- Bring your device to market faster

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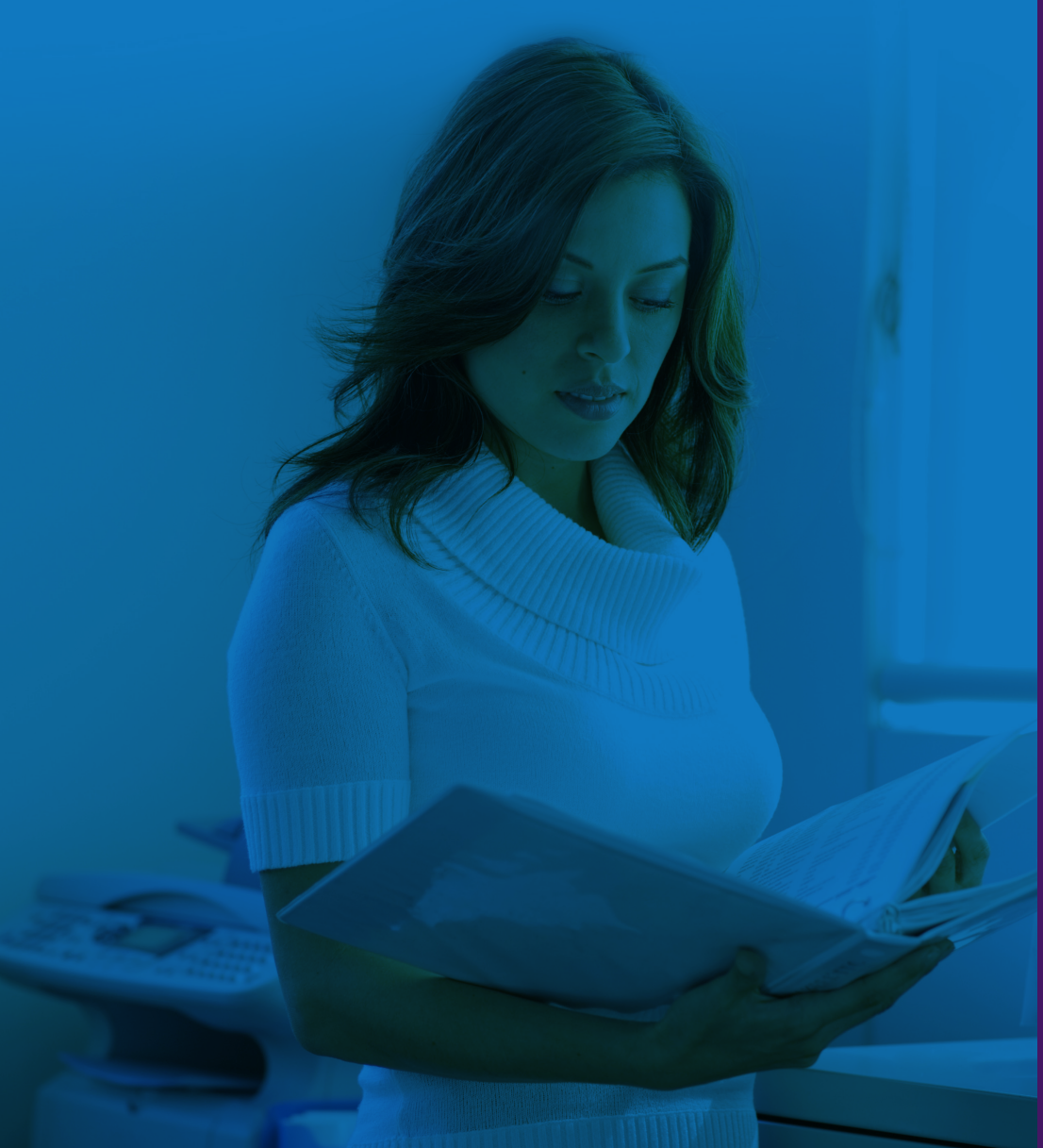
SERVICES



- PROJECT MANAGEMENT
- MONITORING
- AUDITING
- CONSULTING
- DATA MANAGEMENT
- TRAINING
- SAFETY MONITORING
- SITE SUPPORT

PROJECT MANAGEMENT

Are your studies experiencing delays due to limited internal resources or inefficiencies? Our team understands, and we're here to help.

Our highly trained staff will work with yours to **develop a strategy** that helps you achieve your objectives within your time frame. Then we'll **build a plan** to tackle key milestones and **assess progress** throughout the trial. During the process, we will identify opportunities to enhance efficiency without compromising integrity.

Our project management services are designed to accommodate your team's most pressing needs. We can be involved from start to finish or anywhere in between, depending on your goals and your in-house resources.

Some of our project management services include:

- Project planning
- Managing study start-up processes
- Overseeing monitoring to ensure study compliance
- Strategizing to meet enrollment goals
- Coordinating data locks, analyses and study reports
- Supervising study closeout activities, including preparation of regulatory submissions

Benefits of IMARC Project Management

- A single point of contact for your study
- Efficient communication with vendors, team members and site staff across multiple locations
- Expertise managing trials around the world
- A streamlined process that increases your speed to market

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MONITORING

IMARC brings a holistic approach to monitoring, overseeing every aspect of your trial. Whether it is communicating with upper management, following through on issues, tracking trends during studies or creating customized monitoring tools to boost performance, IMARC stays on top of it for you.

We **protect your data integrity, enforce compliance requirements and maintain patient safety** so you can earn approval and bring your device to market faster. Whether you're looking for a partner to manage your sites at every stage or just need someone to make periodic visits, you can count on our team.

Our monitoring services include:

- Managing issues related to site protocol
- Assisting with handling site data queries
- Developing systems for submitting accurate site data in a timely manner
- Providing GCP training and mentoring for site research coordinators

Benefits of IMARC Monitoring:

- Customize your monitoring style
- Easily integrate our team with your site and sponsor teams
- Bring objective oversight and critical thinking to your study
- Streamline communications

AUDITING

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With regulatory inspections on the rise, you need to be sure your site adheres to the most stringent requirements for compliance and patient protection. Our rigorous auditing process is designed to **identify and address issues before the FDA finds them and prepare your team to answer questions with confidence.**

Our comprehensive auditing services are based on the FDA's BIMO checklists and cover every aspect of your study, including protocol, IRB requirements, agreements, sponsor requirements and standard operating procedures. In addition to site GCP audits, we also provide sponsor/CRO audits and vendor qualification audits.

There are unique risks to consider at every stage of a clinical trial. That's why we use a multi-level approach to prepare your team for approval that includes:

1. EVALUATING YOUR SITE, SPONSOR AND VENDORS
2. INSPECTING YOUR FACILITIES, DATA AND PROCESSES
3. PREPARING YOUR STAFF FOR INSPECTIONS AND INTERVIEWS

Benefits of IMARC Auditing:

- Assess performance against research requirements
- Ensure the quality and integrity of data collected
- Identify negative process-level trends
- Receive meaningful deliverables about your study, including a summary of findings, an assessment of your greatest strengths, weaknesses and opportunities, and expert recommendations to achieve compliance

CONSULTING

IMARC provides comprehensive consulting that starts with an assessment of processes. Then our team will work with yours to develop strategies to address any obstacles that hinder performance so you can accelerate progress.

We can help you fine-tune your monitoring and auditing, assess your team and implement support initiatives, and assist with quality system development, to name a few examples.

IMARC's consultants bring an experienced, objective perspective that will help you understand the strengths, weaknesses, obstacles and threats that exist in your team or within your study.

Our consulting services include:

- Quality System Review and Development
- Counsel on GCP Issues
- Development of Oversight Strategies
- Creation of Foundational Documents
- Clinical Planning

Benefits of IMARC Consulting:

- Identify strengths and weaknesses
- Streamline your processes
- Receive concise expert recommendations
- Fine-tune your clinical strategy
- Receive ongoing support

DATA MANAGEMENT

Your data is the lifeblood of your clinical trial. Poor data management practices can quickly derail your study, causing significant delays and even compromising the integrity of your research.

It's important to get this right. IMARC can assist with every aspect of data management — from choosing the right software for electronic data capture (EDC) to monitoring and analyzing data throughout your trial. Then, we build, test, validate and launch the system before your trial begins.

Statistical Analysis

As the FDA introduces further regulation for medical devices (including requiring more real-world evidence), statistical analysis is increasingly important. IMARC's team will help you make sense of your trial data and put it into context so you can respond to inquiries with confidence.

Benefits of IMARC Data Management

- Experience in a wide variety of protocols and EDC systems
- Data managers have previous real-world experience as research coordinators and CRAs
- No one-size-fits all approach; we work with you to determine and implement only what your study needs

TRAINING

IMARC University's training programs have been developed to ensure clinical researchers understand the regulations as well as best practices and how to apply them using critical-thinking skills.

Our training staff brings a broad range of perspectives—with backgrounds ranging from nursing, engineering, medical technology, laboratory research and more—to their roles as research professionals. Many have worked in the research industry for years as research coordinators, monitors, auditors and project managers, and bring a wide array of experiences to training programs.

In-Person Training Solutions

Need to onboard an entire team or provide them with specialized training in specific areas? IMARC University delivers practical, experience-based training from clinical research professionals working in the trenches.

Training can be customized to meet the unique needs (and schedules!) of teams of all sizes. We will bring experienced, dynamic trainers to your team or desired location, or host groups at either of our training facilities in Ohio or Minnesota.

Remote Training, Live via Web Conferencing

When interactive training is a must, remote web conference training offers an alternative to in-person methods to allow for questions in real time, from anywhere in the world. Bring your global team together for remote training, covering a wide range of clinical research topics.

Online Training, Courses on Your Schedule

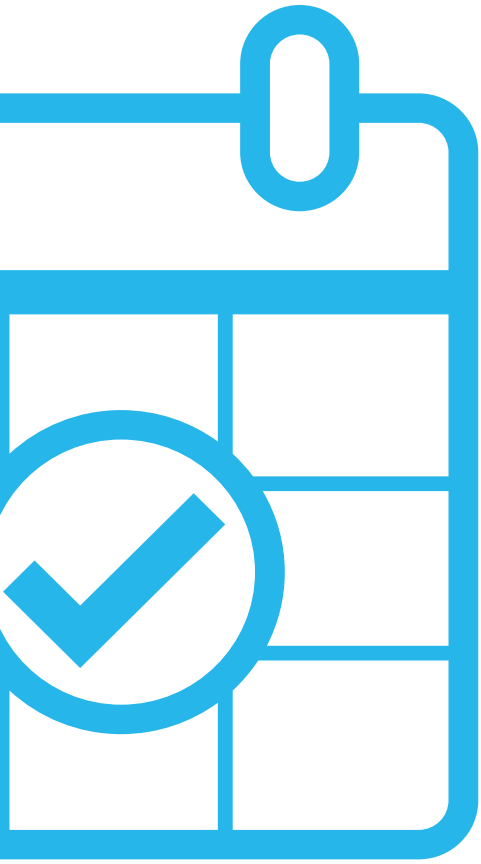
Whether your team members need to prepare for new roles in clinical research or just need a refresher course in the regulations, IMARC University offers affordable, convenient online courses for individuals and teams. Learners can access their courses online anytime and complete them at their own pace.

IMARC University's online courses prepare individuals for a variety of roles within the clinical research field. With a well-trained staff, your team will be using a consistent process that meets the most stringent standards of patient safety and compliance.

Training Solutions For Any Role

Our training is ideal for clinical research associates in many roles at the Sponsor, CRO and Site levels, including:

- Monitors
- Research coordinators
- Investigators
- Project managers
- Auditors
- IRB staff
- Other sponsor and vendor staff members



SAFETY MONITORING

The Data Safety Monitoring Board and Clinical Events Committee are independent boards that add a layer of patient protection and credibility to your research. IMARC will assemble a group of specialists to provide thorough and independent safety oversight through Data Safety Monitoring Boards and Clinical Events Committees.

The DSMB meets periodically to monitor cumulative study safety data, identify concerns and provide recommendations. The CEC investigates individual adverse events and determines an appropriate, objective adjudication of the event so data analysis will be as robust as possible.

IMARC employs physician and professional contractors in several specialties, including cardiovascular, women's health, renal and gastrointestinal therapeutic areas, as well as in emergency medicine and biostatistics. Whether you need a Data Safety Monitoring Board (DSMB), a Clinical Events Committee (CEC) or both, IMARC will assemble these teams and manage relationships with them, ensuring your project meets the highest standards of safety.

Benefits of IMARC Safety Monitoring:

- Proactive human subject protection
- Independent oversight
- Ensuring your data is beyond reproach

SITE SUPPORT

Is your study data being held hostage by busy sites that cause unnecessary delays in reporting and analysis? Are your research coordinators too overwhelmed with essential tasks like providing patient care and managing administrative duties to keep up with data entry? IMARC is here to help.

IMARC provides comprehensive site support that starts with assessing your site and processes. Then our team will work with yours to develop solutions for more effective coordination and deliver results on time, on budget.

IMARC's site support includes:

- Assisting with **remote review of electronic medical records**
- Providing remote data entry
- Call center support
- On-site data and imaging collection support

We go beyond filling the gaps. Our team continuously looks for opportunities to enhance efficiency, improve communication and coordination and ultimately, work smarter.

Benefits of IMARC Site Support:

- Extract and report critical study and safety data faster
- Verify data accuracy
- Provide clean data for analysis sooner
- Free up **staff to focus on achieving other objectives**

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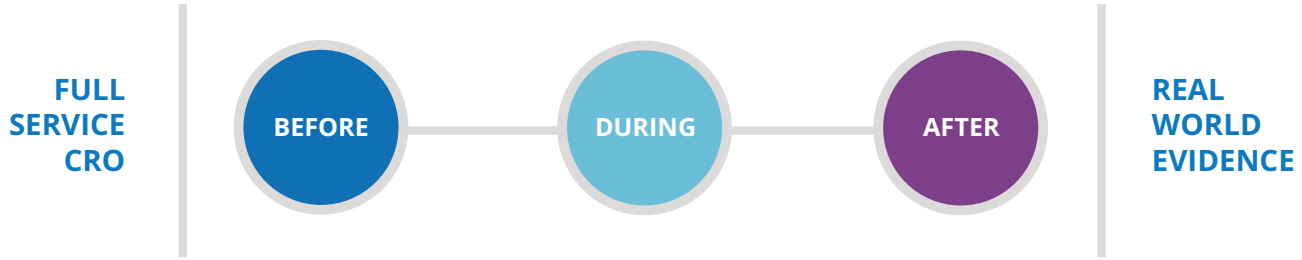
IMARC SERVICES MEET YOUR NEEDS AT EVERY STAGE

Our global, full-service team is capable of stepping in at any point in your clinical research trial, but we offer the most value when we're involved from start to finish. This way we can offer comprehensive planning, consulting and oversight from all angles, ensuring your data is flawless and your study integrity is beyond reproach every single time.

OUR SERVICES

A TRUSTED COMPLIANCE PARTNER

Supporting You At Every Stage In Your Trial



FULL SERVICE CRO

IMARC's team of monitors, auditors and experienced clinical research professionals provide comprehensive support, from planning to post-market data collection.

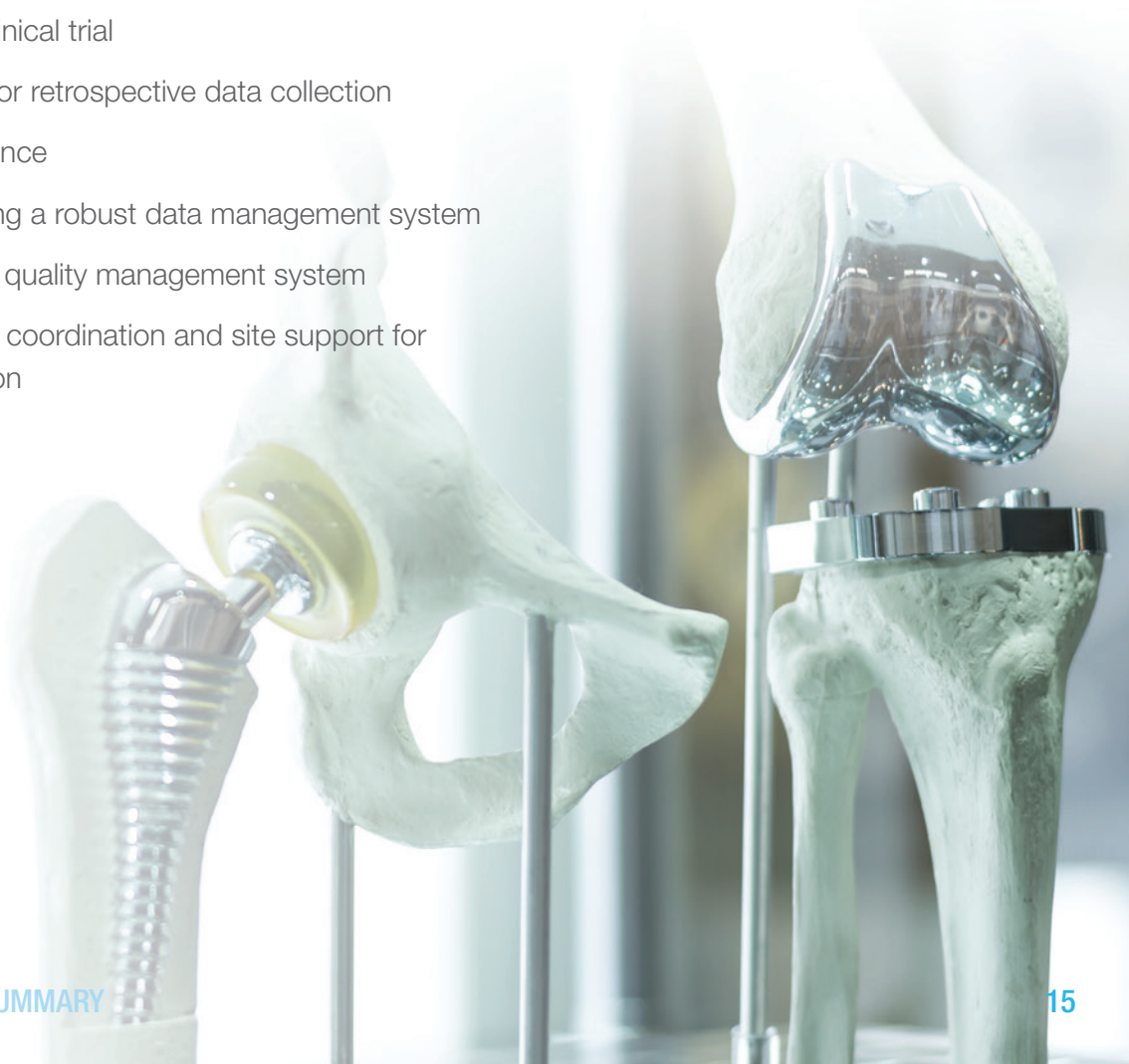
COMPLIANCE WITH EU REGULATIONS MDR AND IVDR

Two new regulations are significantly impacting companies that do business in Europe: the Medical Device Regulation (MDR) and the In Vitro Diagnostics Regulation (IVDR). These new regulations have a wider scope, requiring data-based evidence for both new and existing medical devices.

As you consider what additional data you may need to comply with the new regulations, IMARC can help you develop a plan to obtain it.

Our team can also support you in your data collection efforts, including:

- Conducting a full-blown clinical trial
- Developing your strategy for retrospective data collection
- Collecting real-world evidence
- Choosing and implementing a robust data management system
- Developing or improving a quality management system
- Providing remote research coordination and site support for retrospective data collection



MORE TRIAL, LESS TRIBULATION

As a global, full-service medical device CRO, IMARC has over 20 years of experience helping manufacturers conduct compliant clinical research and ultimately earn approval.

Our team can help yours overcome the chaos of a complex trial so you can focus on what matters most.

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

To schedule a consultation, contact John E. Lehmann, Director of Business Development, 440-801-1540, jlehmann@imarcresearch.com