IMARC Research, Inc.

EXECUTIVE SUMMARY

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WE'LL EARN YOUR APPROVAL.

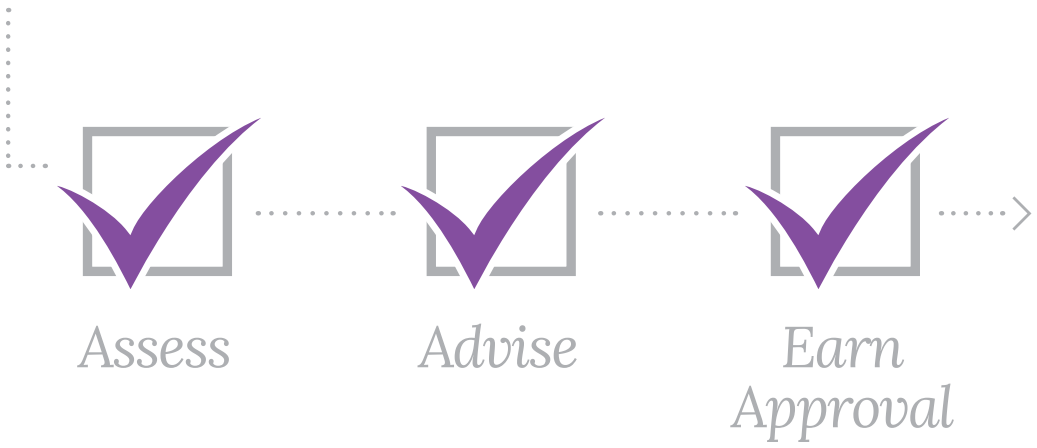
WHO WE ARE

IMARC is a leading clinical research organization that ensures compliance for studies of medical devices and biotechnologies. Founded in 1999 by Sandra Maddock, a former research coordinator with a passion for protecting patients, our team is committed to ensuring compliance at every stage so your team can reach the finish line faster.

As an ISO-certified company, we use standardized processes and best practices we have perfected over nearly 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, providing both our clients and staff with easy travel access.

YOUR PARTNERS
in Compliance



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OUR MEDICAL DEVICE EXPERTISE

Types of Research

- Pilot/Feasibility Studies
- IDEs
- 510(k)s
- Post approval studies
- Investigator Initiated IDEs

Study Experience

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

OUR SERVICES CAN HELP YOU:

- Manage complex trials
- Address top FDA failures
- Secure FDA approval
- Bring your device to market faster

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SERVICES

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

MONITORING

IMARC brings a holistic approach to monitoring, overseeing every aspect of your trial. Whether it is assessing site compliance, 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 ensure 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:

- Conducting assessment, initiation, periodic and closeout visits
- Assisting with handling site data queries
- Developing systems for submitting accurate data in a timely manner
- Providing GCP training and mentoring for site staff

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

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.

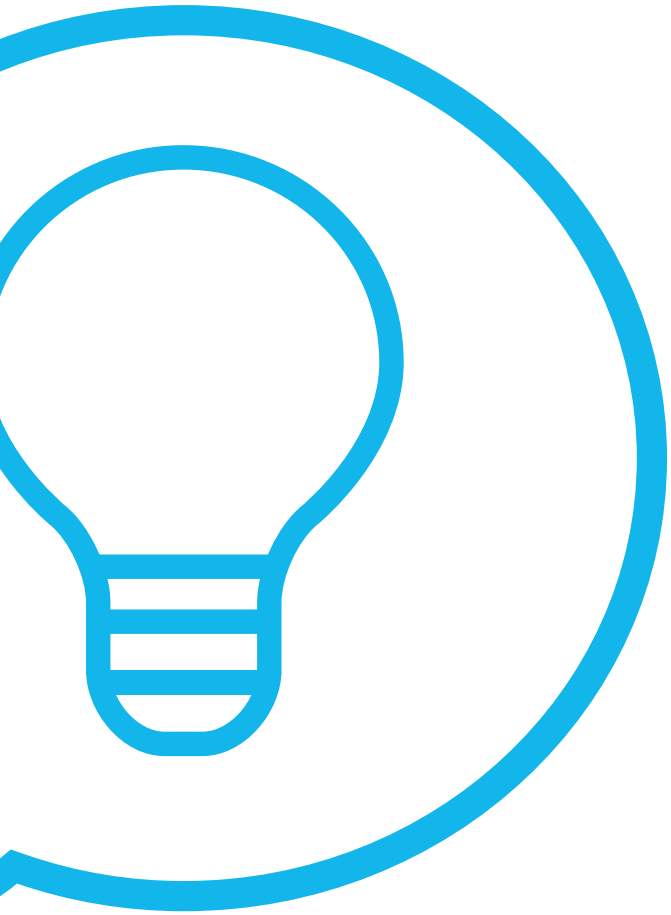
Our comprehensive auditing services are based on the FDA's BIMO checklist and cover every aspect of your study, including protocol, IRB requirements, agreements, sponsor requirements and standard operating procedures. In addition to GCP audits of investigational sites, we also provide sponsor/CRO audits, vendor qualification audits and IRB 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. ASSESS PERFORMANCE AGAINST RESEARCH REQUIREMENTS
2. ENSURE THE QUALITY — AND INTEGRITY — OF DATA COLLECTED
3. SYNC OBSERVATIONS WITH REGULATORY COMPLIANCE STANDARDS THROUGH CORRECTIVE AND PREVENTATIVE ACTION RECOMMENDATIONS
4. OVERALL IMPROVED COMPLIANCE, OPTIMAL READINESS FORINSPECTION, AND ULTIMATELY, HIGH-QUALITY STUDIES THATSUPPORT MARKETING SUBMISSIONS

Benefits of IMARC Auditing:

- Assess monitoring effectiveness
- Identify negative process-level trends
- Receive meaningful deliverables, including a summary of findings, an assessment of your greatest strengths, weaknesses and opportunities, and opprotunities and expert recommendations



CONSULTING

IMARC provides comprehensive consulting that starts with assessing your site and 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 study.

Our consulting services include:

- Clinical Planning
- Quality system development
- Counsel on GCP issues
- Development of oversight strategies
- Creation of foundational documents
- International support

Benefits of IMARC Consulting:

- Identify strengths and weaknesses
- Streamline your processes
- Receive concise expert recommendations
- Fine-tune your monitoring strategy
- Accelerate your auditing strategy
- Receive ongoing 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
- Conducting ongoing risk analysis
- Qualifying and managing vendors
- Managing study start-up processes
- Overseeing monitoring to ensure study compliance
- Strategizing to meet enrollment goals
- Ensuring timely data submission and resolution of data queries
- 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

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.

Training Solutions For Any Role:

Our training is ideal for clinical research professionals 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 MANAGEMENT

The Data Safety Monitoring Board (DSMB) and Clinical Events Committee (CEC) 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.

Our Approach to Safety Management:

IMARC operates several safety monitoring boards with a variety of therapeutic capabilities represented by the board members and protocols under review. IMARC will manage all DSMB/CEC activities through the DSMB/CEC Coordinator, including:

- Screening and assembling of board members
- Coordinating meetings and distributing information
- Hosting in-person or remote meetings
- Providing high-quality documentation
- Managing member payments and compiling payment information for Sunshine Act compliance

A robust quality system will guide the management of your DSMB or CEC to ensure members are well-qualified, meetings are handled expertly, and independent safety oversight of your study will be in good hands.

Benefits of IMARC Safety Management:

- 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 support
- 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 in-house staff to focus on achieving other objectives

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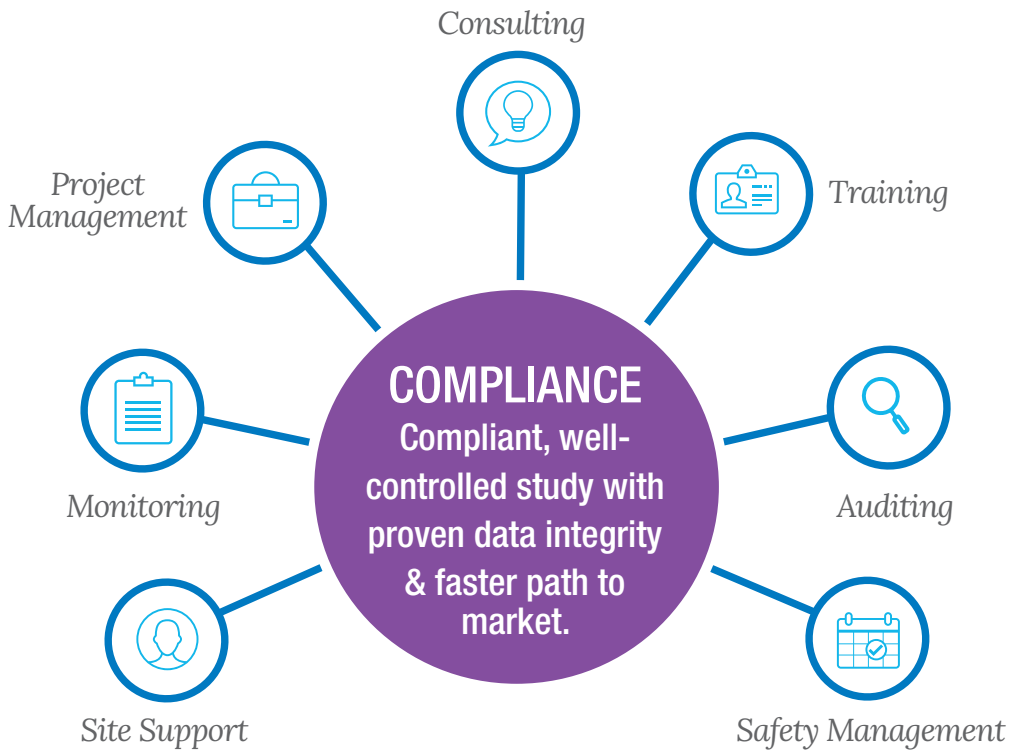
IMARC SERVICES MEET YOUR NEEDS AT EVERY STAGE

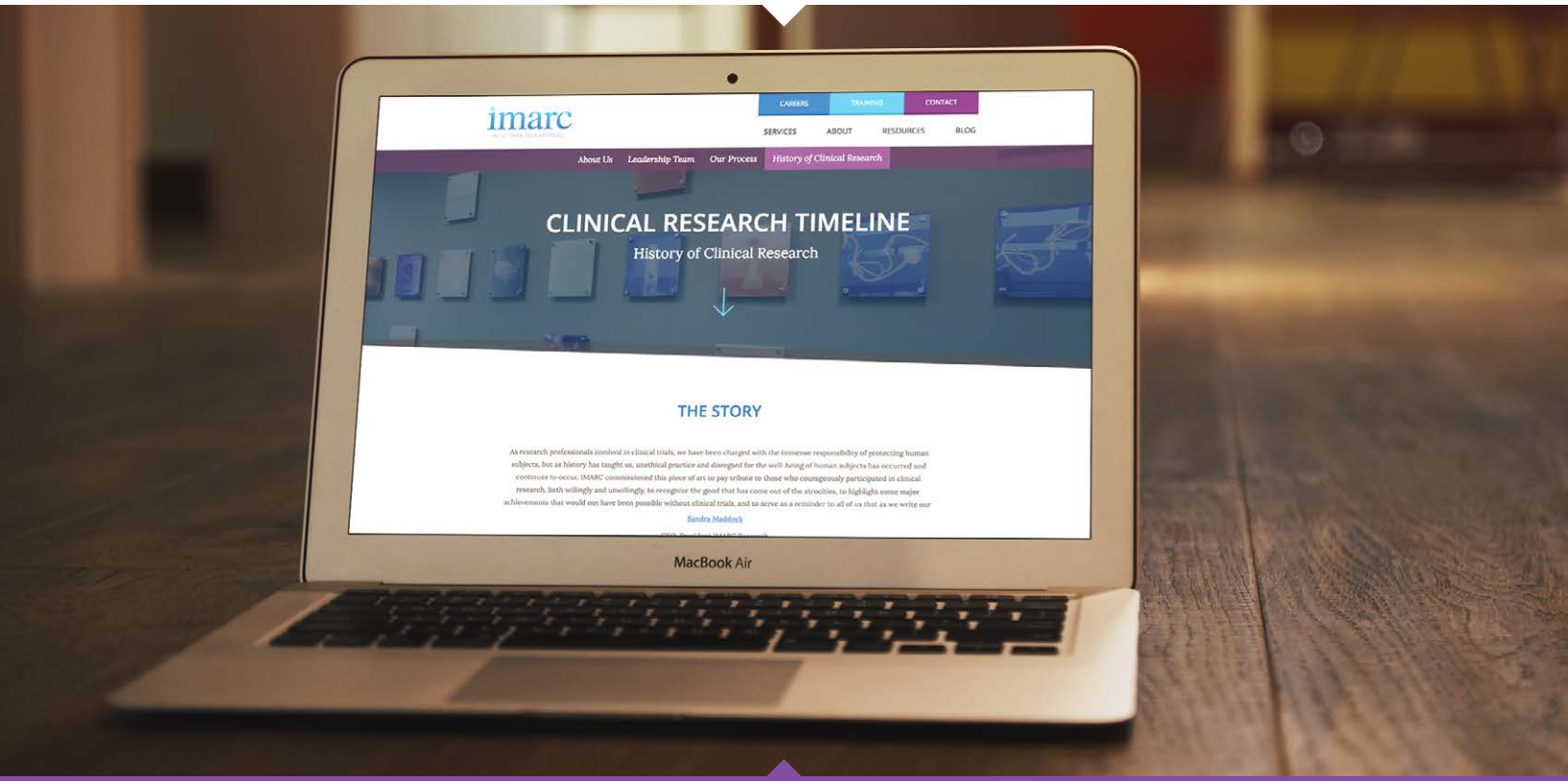
Our team is capable of stepping in at any point in your clinical research trial, but we offer the most value when we're involved from start to finish. This way we can offer comprehensive planning, consulting and oversight from all angles, ensuring your data has integrity and human subjects are protected.

PARTNERS IN
ensuring compliance



HISTORY OF CLINICAL RESEARCH

As clinical research professionals, we often take human subject protections and protocols for granted. Unfortunately, many advancements in ethics and human subject protection have emerged as a result of those who paid a high price—sometimes the ultimate price. The artwork in IMARC's lobby pays tribute to those who have courageously participated in clinical research, both willingly and unwillingly, since the beginning of time. It serves as a reminder of the immense responsibility we have as researchers to protect human subjects above all else.

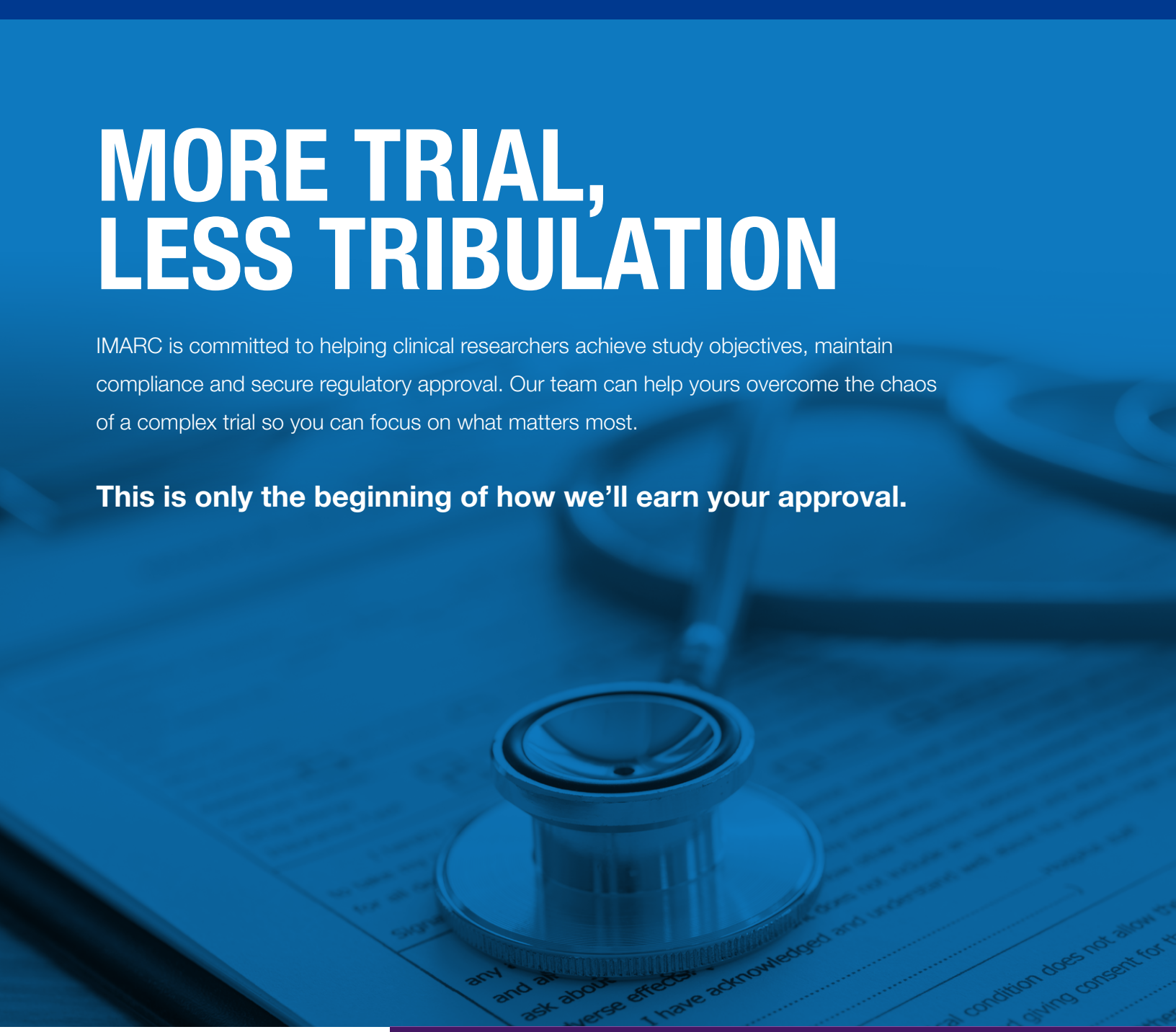


EXPLORE OUR CLINICAL RESEARCH TIMELINE

MORE TRIAL, LESS TRIBULATION

IMARC is committed to helping clinical researchers achieve study objectives, maintain compliance and secure regulatory approval. Our team can help yours overcome the chaos of a complex trial so you can focus on what matters most.

This is only the beginning of how we'll earn your approval.



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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