IMARC Research, Inc.

Executive Summary

Independent

Monitoring

Auditing

Research

Consulting

imarc

WE'LL EARN YOUR APPROVAL.

Introduction

IMARC Research was founded in 1999 by Harold and Sandy Maddock who both had a passion for patients and a belief that there was a better way to provide oversight for clinical research studies. These principals have helped fuel IMARC's steady growth and remain core principles for the company. The company is headquartered in Strongsville, Ohio, just minutes from Cleveland Hopkins International Airport, providing both our clients and staff with easy travel access.

For background, IMARC assists the clinical research community in the pursuit of FDA and worldwide approvals. Our effectiveness is built on preparing, educating, complementing and guiding site teams from Day 1 — to control the complex management of trials via cost-effective monitoring, auditing and training services — which results in the support, proof and assurance they seek to overcome chaos caused by complexity while achieving compliance through consistency. Providing committed, competent and confident consultation is how IMARC sets the highest standards for site outcomes and study partnerships.

Medical Device *Expertise*

- **Sponsor Funded Research**
  - Pilot/Feasibility
  - IDEs
  - 510(k)s
  - Post approval studies
- **Investigator Initiated IDEs**
  - Site perspective
  - Sponsor perspective
- **Study Experience**
  - Cardiovascular
    - Interventional
    - Peripheral
    - Vascular
  - Orthopedics
  - IVD
  - Neurological
  - Wound Care
  - Pediatrics
  - Many others…

Benefits *of* IMARC Involvement

- **Strong track record with FDA**
  - IMARC sites have never received an FDA warning letter
- **Ability to manage complex trials**
- **IMARC's core services address top FDA failures**
  - Inadequate monitoring
  - Securing compliance
- **Provide independent third-party oversight**
- **Involvement can help speed device to market**
- **Company culture**
  - Top management involvement
  - Strong support

Monitoring

Your Site. *Our Eyes.*

Monitoring sites start with understanding how to manage them. IMARC has extensive experience doing both. Are your studies suffering setbacks from slow enrollment or submission of critical data? Do costly delays keep pushing you further away from approval? There are solutions — and IMARC has them. Whether from the start, or during particular phases, our highly-trained monitors are qualified to take the burden off you and act as site liaisons to help:

- **Manage site protocol-related issues**
- **Assist with handling site data queries**
- **Develop systems for submitting accurate site data in a timely fashion**
- **Provide GCP training and mentoring for site research coordinators or replacements**
- **Alert site team members to pressing issues**

CLINICALLY SOUND SITE EXPERIENCE

- ICU
- CCU
- Post-Cardiac Care
- Post-Anesthesia
- Neurology
- Medical / Surgical
- Public Health
- Podiatry
- Oncology
- Psychiatry
- Women's Health

IMARC's Approach & Philosophy

- **Customized monitoring style**
  - More than x=x and y=y
  - Use own SOPs or sponsor's SOPs
- **Value the sponsor's relationship with the sites**
  - Streamline communication
  - Integrate easily with site and sponsor teams
- **Strong problem solving**
- **Exceed expectations (reports, follow-up, communication)**
- **Quality in and quality out**

Auditing

A "Top-Down" look at compliance for your study.

With FDA and International inspections on the rise, so are stress levels of everyone involved in clinical studies. IMARC provides the specialized independent auditing support services you need to survive today's rigid regulatory requirements — not only to ensure compliance, but also to protect patients. There are many steps throughout our process designed to put you – and keep you – in complete control.

For starters:

Step 1: Assess how your site is performing.

Step 2: Ensure the quality – and integrity – of data collected.

Step 3: Sync your site status with regulatory compliance standards.

The Result: Overall cost savings, optimal readiness for inspection, and ultimately, approval.

Prepare for Approval

- Identify and fix issues before the FDA finds them.
- Get ready for inspections by knowing what to expect.
- Address compliance concerns and gain reassurance through Special Request Audits.
- Verify that vendors have the experience to do their jobs.
- Prep your team with interviewing and coaching sessions.

Benefits of IMARC Auditing

- **Determine monitoring effectiveness**
- **Identify negative process-level trends**
- **Provide meaningful deliverables**
  - Comprehensive reporting
    - Summary of findings
    - Assessment of their degree of reach and degree of impact
    - Expert recommendations

RESEARCH TRAINING & DEVELOPMENT

Well-run, compliant studies result from well-trained staff.

IMARC Trainers have prepared clinical research teams throughout the world for more than 10 years. Our approach to hands-on training empowers your team to competently handle any site requirement they put their hands on.

- **Who we train**
  - Sponsors
  - Monitors
  - Site Staff
    - Investigators
    - Research Coordinators
  - IRB members
- **Sponsor-investigator training**
- **Local and national presentations**
  - ACRP, MAGI, SoCRA, BioOhio Regulatory Forum

Training for Trials Worldwide

- Human Subject Protection
- GCP Compliance
- Introduction to Research Coordinating
- Monitoring 101
- GCP, JGCP and ICH Guidelines
- FDA Regulations:
  21 CFR 11, 50, 54, 56, 312 and 812

Benefits of IMARC Training

- **Onsite, honed to meet attendees' needs**
- **Industry thought leaders**
- **Interactive training**
- **Global experience**
- **Simplify regulations - FAIR Shake™**

Giving Your Studies a fair((shake))™

Be trained to:

- Implement the framework required to stay compliant.
- Navigate the regulatory maze with GCP training tailored specifically to your study team.
- Run your own investigator-initiated IDE or IND study with existing staff.
- Manage specific phases or processes while staying focused on achieving approval.

Consulting

Consulting that Puts and Keeps You in Control.

Need a qualified expert to bounce ideas off or challenge your thinking? Tap into our knowledge base and ensure that what works gets done and what doesn't work gets bounced. Another factor that can make or break your study is unexpected issues that pop up. IMARC Consultants have the monitoring and auditing experience to adapt quickly, react proactively and intelligently balance your priorities.

- **Fine-tune your monitoring strategy**
- **Accelerate your auditing strategy**
- **Assess your study team**
- **Roll-out enrollment support initiative**
- **Build your team's confidence with knowledge**

SOP Monitoring Support

- Investigative Sites
- GCP Audits
- Escalation Plans

SOP Creation Services

- CROs
- Investigative Sites

SOP Assessment Analysis

- U.S., European and Japanese Sponsors
- CROs
- Investigative Sites

Benefits of IMARC Consulting

- **Identification of strengths and weaknesses**
- **Streamlined processes**
- **Concise expert recommendations**
- **Clear vision forward**
- **Ongoing Support**

More Trial *and* Less Tribulation

Assisting clinical researchers achieve site study objectives is the main focus at IMARC. Expect to find the support, proof and assurance you need to overcome chaos caused by complexity while achieving compliance through consistency. Here's how:

CONTROL. *Take more of it.*

Leverage cost-effective monitoring, auditing and training services to stay in command from start to finish.

COMPLIANCE. *Your struggle stops here.*

Overcome instability created by overworked, undermanned or inexperienced staff during specific study stages.

COMPETENCE. *Knowledge you can trust.*

Enjoy the security of knowing that sites monitored from the start by IMARC have never received a warning letter.

CREATIVITY. *Accelerate progress.*

Count on our ability to critically think through issues that yield creative solutions.

COMMITMENT. *Set the highest site standards.*

Focus on your research while we handle logistics and logjam prevention.

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

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WE'LL EARN YOUR APPROVAL.

To schedule a presentation, contact John E. Lehmann, Director of Business Development **440.801.1540**

22560 Lunn Road, Strongsville, Ohio 44149 • **tel** 440.801.1540 • **fax** 440.801.1542
info@imarcresearch.com • **imarcresearch.com**