SAFETY MANAGEMENT

imarc
WE'LL EARN YOUR APPROVAL.

OUR APPROACH IN 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 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 customized Safety Management plan 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.

Protect Your Patients… and Your Study's Integrity

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.

Review…Assess…Recommend

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 various specialties, including cardiovascular, women's health, renal and gastrointestinal therapeutic areas, as well as in emergency medicine and biostatistics. Whether you need a DSMB, a CEC or both, IMARC will assemble these teams and manage relationships with them, ensuring your project meets the highest standards of safety.

See the Whole Picture With Our Full Range of Services

Our safety management services can stand alone or complement any of the full range of services we provide, including:

- **Monitoring**
  Providing critical thinking, practical experience and full oversight to your trial
- **Auditing**
  An efficient, cost-effective way to identify compliance issues before the FDA does so you can approach your inspection with confidence
- **Training**
  Comprehensive, cost-effective and convenient training programs to ensure your team understands the regulations and how to apply them using critical thinking
- **Project Management**
  Coordinating with team members and vendors to prevent delays and keep your project moving forward
- **Site Support**
  Handling paperwork, data entry and other site responsibilities so on-site staff can focus on subject enrollment and patient care
- **Consulting**
  Helping your team handle quality system development, compliance concerns or other procedural issues

SAFETY MANAGEMENT: A CRITICAL ELEMENT IN COMPLIANCE

Ensuring the safety of human subjects is your most important clinical research responsibility. It's also essential to managing compliance and ultimately in achieving regulatory approval. With IMARC's safety services, you can be confident your trial is compliant and on track so you can bring your device to market faster.

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To learn more, contact John E. Lehmann, Director of Business Development at 440.801.1540
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