NAMSA®

Clinical Study Management
Data Safety - Clinical Events

Clinical Study Management

In medical device product development, the clinical study phase is the most time consuming, least predictable, most expensive and most important. NAMSA uses optimal strategies and tools to guide you through, from study design to final clinical report. Our engagements range from á la carte to full service, depending on your needs.

People and Procedures

The NAMSA advantage starts with our clinical study management experts, averaging more than 20 years in the medial device industry. Our experts have experience running all manner of clinical studies, from first-in-man procedures through multi-center randomized global IDE trials.

Each NAMSA client study undergoes a periodic internal review where executives and project management peers scrutinize key factors such as quality, costs, timelines and potential risks.

NAMSA's clinical trial service organization is ISO 9001:2008 certified. We have well-established SOPs for the planning, initiation, and conduct of studies—including template documents, checklists and forms. We are also meticulous about planning and communicating with both sponsors and investigative sites, and we adhere to GCP, ICH and FDA standards for data integrity, patient protection and regulation.

Data Safety - Clinical Events

NAMSA provides expert support for clinical events committees (CECs) and data monitoring committees (DMCs). For many medical device manufacturers, managing the administrative details and workload of these functions is highly burdensome. We lighten your load by establishing and managing these committees on behalf of the sponsor.

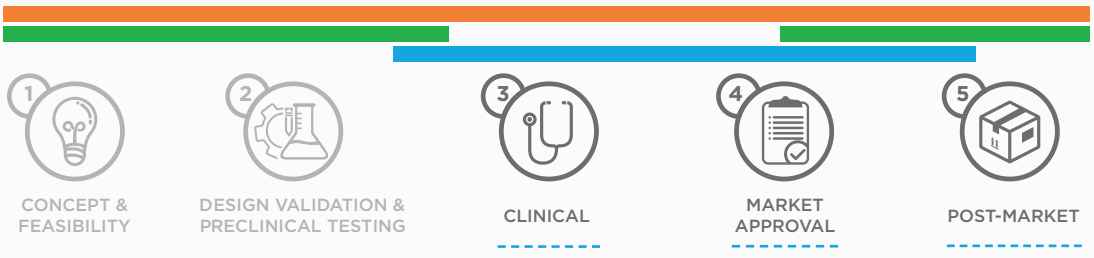
NAMSA follows a well-characterized process for documenting and reporting adverse events (AEs) that occur during investigational studies. It is designed to ensure the AEs are reported using uniform guidelines and are in compliance with applicable global regulatory requirements.

Common CEC/DMC Tasks

- Developing committee charter and procedures
- Interviewing and recruiting committee members
- Negotiating agreements and remuneration with committee members
- Preparing source document checklists, adjudication forms and event narratives
- Scheduling meeting location and dates
- Facilitating meetings
- Recording meeting minutes
- Writing and distributing follow-up reports

NAMSA typically supports anywhere from 15 to 20 manufacturers each year with their event adjudication and data safety reporting needs.

Medical Device Development Process & The MRO® Approach



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