Site Management Organization

Module 6 Topic 4

Definition

- Site Management Organization (SMO) is an organization that provides clinical trial related services to a Contract Research Organization (CRO),a Pharmaceutical company, a biotechnology company, a medical device company or a clinical site
- A SMO means a person that assumes, as an independent contractor with the clinical investigator, one or more of the regulatory obligations of a clinical investigator, e.g., preparation and maintenance of case histories, ensuring compliance with IRB review and informed consent requirements, AE reporting etc

- SMO’s usually have a network of clinical research sites which they manage and work with dedicatedly…
- SMO’s may manage all or a part of clinical research activity at a clinical research site based on their understanding and agreement with the head of the clinical research site, which may be a hospital or a private practice.

- SMO can be a cost and time savers for the sponsor companies and CRO's for initiating a multicentric clinical trials.
- Primary role of SMO is to provide managerial oversight to a group of sites performing research.
- SMO can either have a master legal agreement with medical institution their work with or a equity stake in ownership of the site. In any case SMO has exclusive relationship with site.

Responsibilities

- Contract
- Submission for Institutional Review Board or Independent Ethics Committee (IRB/IEC) approval. In Europe, submission to Ethics Committee is often done by sponsor or by CRO, i.e. not by SMO
- Patient Counseling
- Patient Recruitment
- The scope of an SMO's responsibility is limited to the 'site' and hence the eponymous title. Some (but not all) of the responsibilities include:

Responsibilities

- Patient Follow-up
- Informed consent form (ICF) translation into vernacular languages
- Site initiation and trial close-out operations
- Trial-related documents archival and maintenance

Responsibilities

- Reporting serious adverse events to the Sponsor or CRO and the IRB/IEC
- Ensuring protocol compliance
- Advising & alerting investigators of potential protocol violations
- Advising & alerting investigators of potential ICH-GCP violations

CRO vs. SMO-Similarities and differences

- Both are contractors the principal differences are with whom they contract, services contracted for, and their legal liability
- CROs contract with sponsors and are explicitly regulated
- CROs are legally liable for the obligations they assume
- SMOs contract with clinical investigators and are not explicitly regulated
- SMOs are not legally liable for the obligations they assume

Examples of SMOs in India

- Excel Life Sciences
- Cytespace Research Private Limited
- D2L Technologies
- JSS Pharma