STUDY MANAGEMENT: CLINICAL RESEARCH ORGANIZATIONS

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- CROs: Why Do We Need Them?
  - Limited resources/Augment in-house personnel
  - Access to large number of patients/sites
  - Accelerated projects
  - Development cycles of products
  - Increased products in the development pipeline
  - International studies
  - Joint collaborations
  - Marketing Support

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- CROs: How Do We Choose Them?
  - Ownership structure
    - Independent, Confidential
    - Financial stability
    - Professionally staffed
  - Experience
    - GCP, Global regulatory experience, International standards
  - References
  - Specialization
  - Standard Operating Procedures
    - Match between Sponsor and CRO

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- CROs: How Do We Choose Them? (cont.)
  - Quality assurance
  - Infrastructure
    - Location, International network, Data security, Electronic database/Communication

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- CROs: What Have We Learned?
  - Sponsor has ultimate responsibility for the studies
    - Communication with all parties involved
    - Train CRO personnel
    - “Manage the study managers”
  - Limited experience in the Medical Device Industry
  - Expectations must be clearly documented
    - Clearly identify obligations of all parties involved
    - Set milestones to measure performance
  - Investigators/study coordinators must communicate any problems with the CRO to the Sponsor

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- CROs: What Have We Learned? (cont.)
  - Turnover of CRO staff can be problematic
    - Lack of consistency at study site
    - Re-training of new CRO personnel
  - CROs are expensive
  - Quality of work performed
  - Sponsor's knowledge on final product
    - Limited due to lack of day-to-day communication with study site staff