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Decisions, Decisions, Decisions: A Site Level Perspective

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Sponsor Decisions that Increase the Chance of Failure

- Last minute recruitment campaigns – stressful for sites, CRO's and sponsors
- Overly complicated inclusion/exclusion criteria
- Inadequate subject compensation
- Burdensome visits that increase the likelihood of subject dropouts
- Choosing vendors that are actually beta testing on the sites
- Reliance on multiple vendors

Sponsor Decisions that Increase the Probability of Success

- Site Advisory Board – starting with protocol development and continuing throughout the study
- Protocol flexibility in design
- Sponsor involvement throughout the trial
- Realistic expectations for enrollment

Sponsor Decisions that Cut Both Ways

- Communication pathway
- Involvement/Role of Medical Monitor
- Number and type of assessments

Sponsor Decisions that Motivate Sites

- Actual investigator meetings
- Inclusion of recruitment staff at multiple touchpoints
- Clearly written protocols that do not rely on semantic interpretations
- Knowledgeable CRA's that have been trained in the indication
- Limiting heavy procedure days