



The Investigator As Trusted Partner

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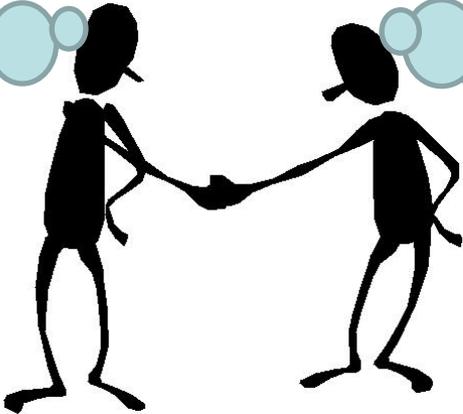
FDA

U.S. Department of Health and Human Services

Food and Drug Administration



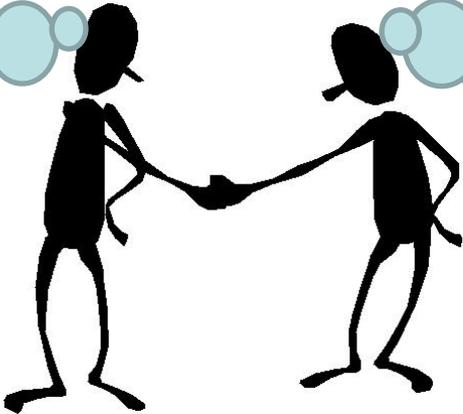
Partners have Different POV and Concerns



Do they know the study?
Resources and staff?
Quality & GCP?
Can they enroll adequately?

Sponsor

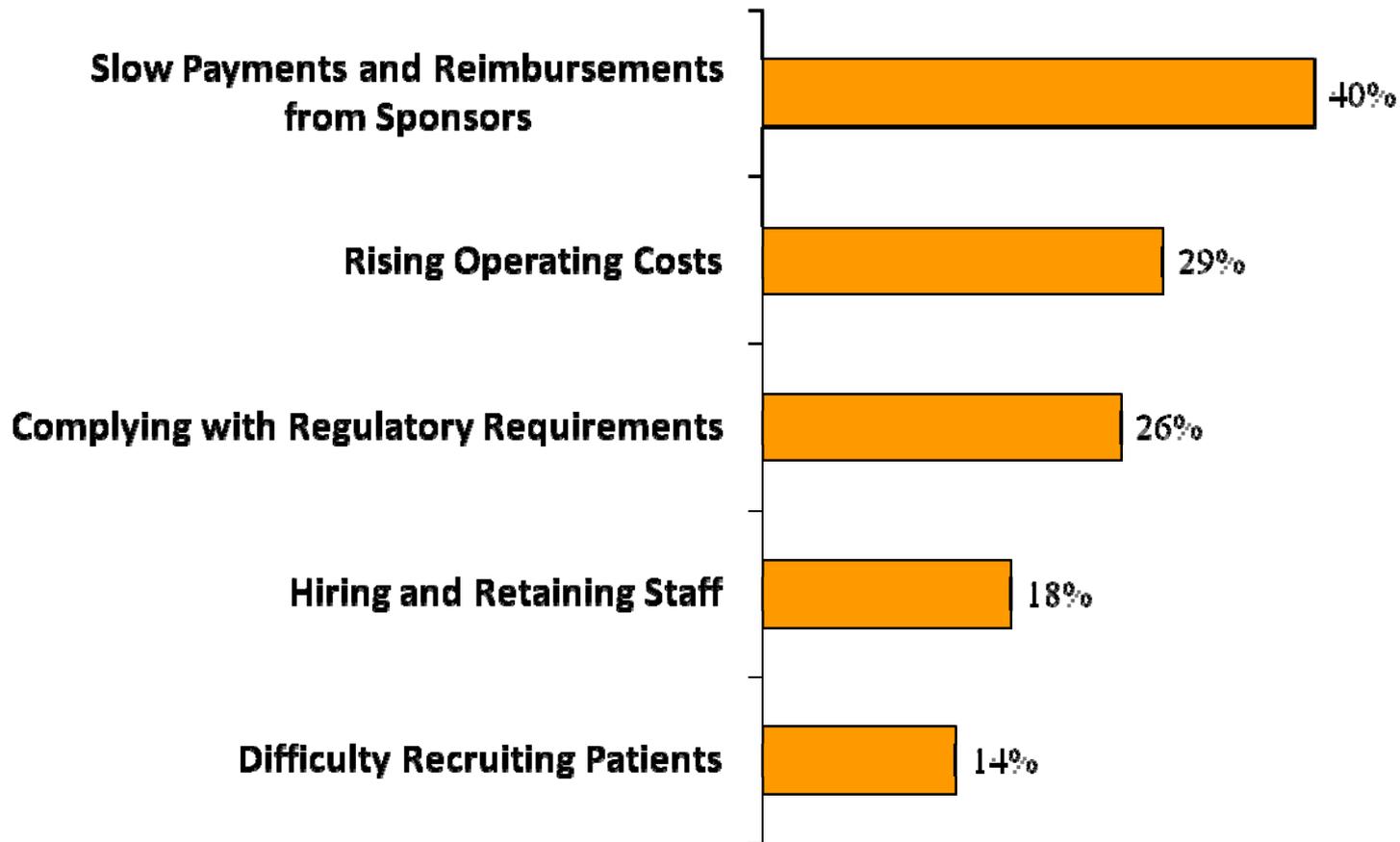
Investigator



Some of the inclusion/exclusion just doesn't make sense.
Is this study worth my time/interest?
Do they have adequate funding?
Who is the CRO?

Top Investigative Site Operating Concerns

(Percent of Respondents)



Source: CenterWatch Survey of 347 Investigative Sites (2009)

Ken Getz from Site Solutions Summit 2010





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- Protocol review for feasibility
 - Do you have the staff, time, equipment and space to do this study?
- Communication with Sponsor
 - Expectations to be communicated clearly and often... in writing.
- Rapid study start-up
 - Turn around time for CDA, contract & budget, regulatory documents, etc.
 - Local or Central IRB

Note: Approximately 7% of ALL sites actually deliver what they proposed in the feasibility assessment

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- Timely enrollment
 - Do you have the patients in your practice or will need to advertise for them? If advertising is used, what is the best media for a particular indication? How long will it take to find the people who meet the criteria?

Notes:

- *90% of all clinical trials fail to meet enrollment target*
- *20% of sites are responsible for 50+% of the patients;*
- *20% of sites fail to enroll a single patient;*
- *30% under-enroll*

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- Efficient, and businesslike operations
 - Do you know your costs? Will the budget accommodate the resources required for this study: time, staff, OH, equipment, drug and materials storage, long-term storage, etc.?
- Adherence to FDA Regs/ICH Guidelines
 - Is your staff familiar with the regs/guidelines or do they need training?
 - Do you have SOPs in place?
 - Do you have an internal audit program?

Note: 14% of all active sites receive at least one complaint for non-compliance and fraud annually

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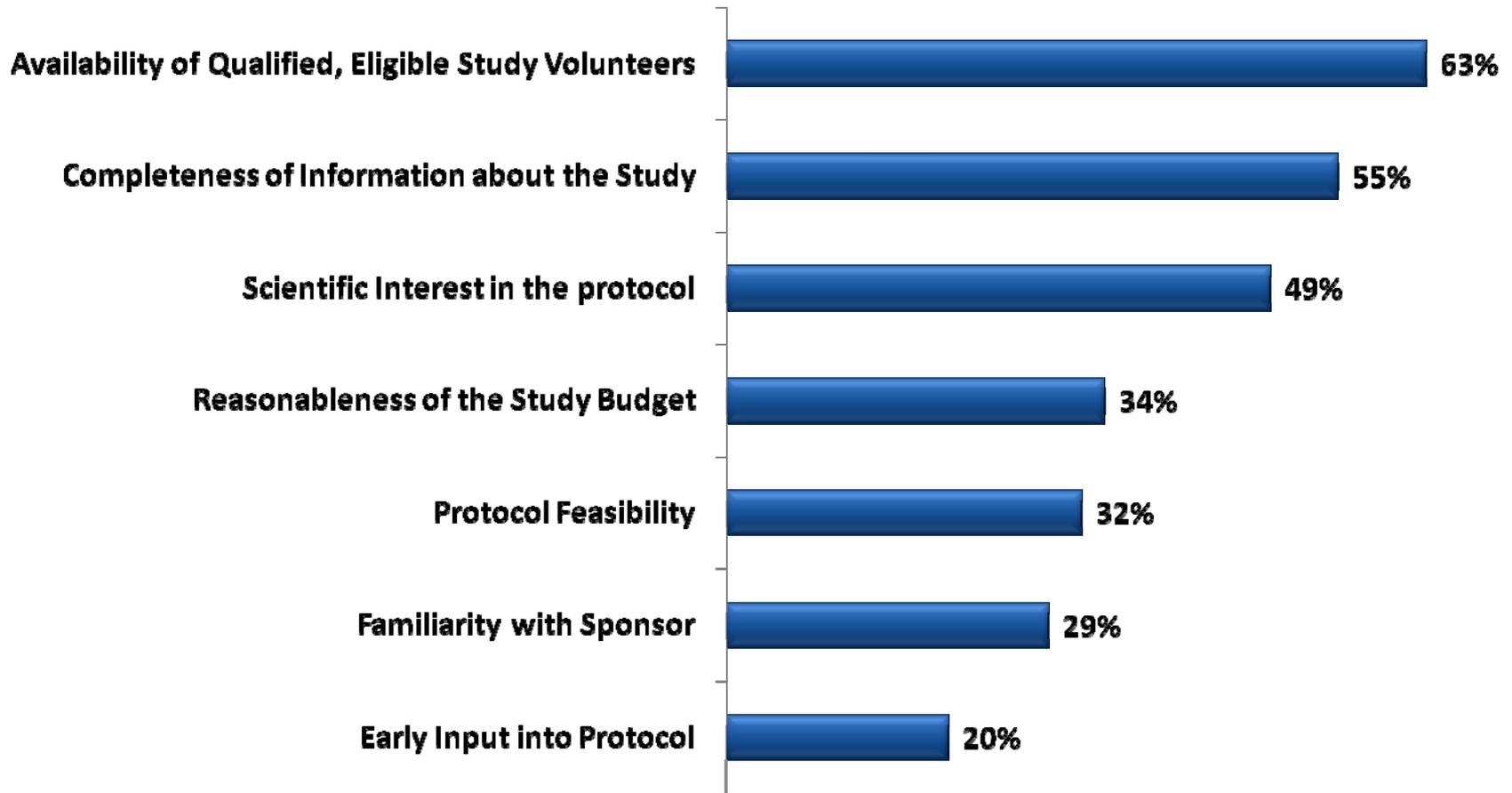
- Study staff
 - Study coordinator: What qualifications do you need in a study coordinator? What kind of training will be required?
 - Regulatory, legal and budgeting: who is going to handle these items?
 - Sub-investigator: Who is going to be the sub-I and what are they expected to do?
 - Communication with staff: how is it done and how documented – staff meetings, hallway meetings?



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- Delegation of duties
 - What can be delegated? What kind of training is required for duties that are delegated.
- Training
 - When is training to be done?
 - Who is doing the training?
 - How is it documented?

Supporting Sites for Success: Top Factors Ensuring Best Performance



Sources: TCSDD Survey of 3,516 Sites, 2010

