



The Investigator: A Trusted Partner

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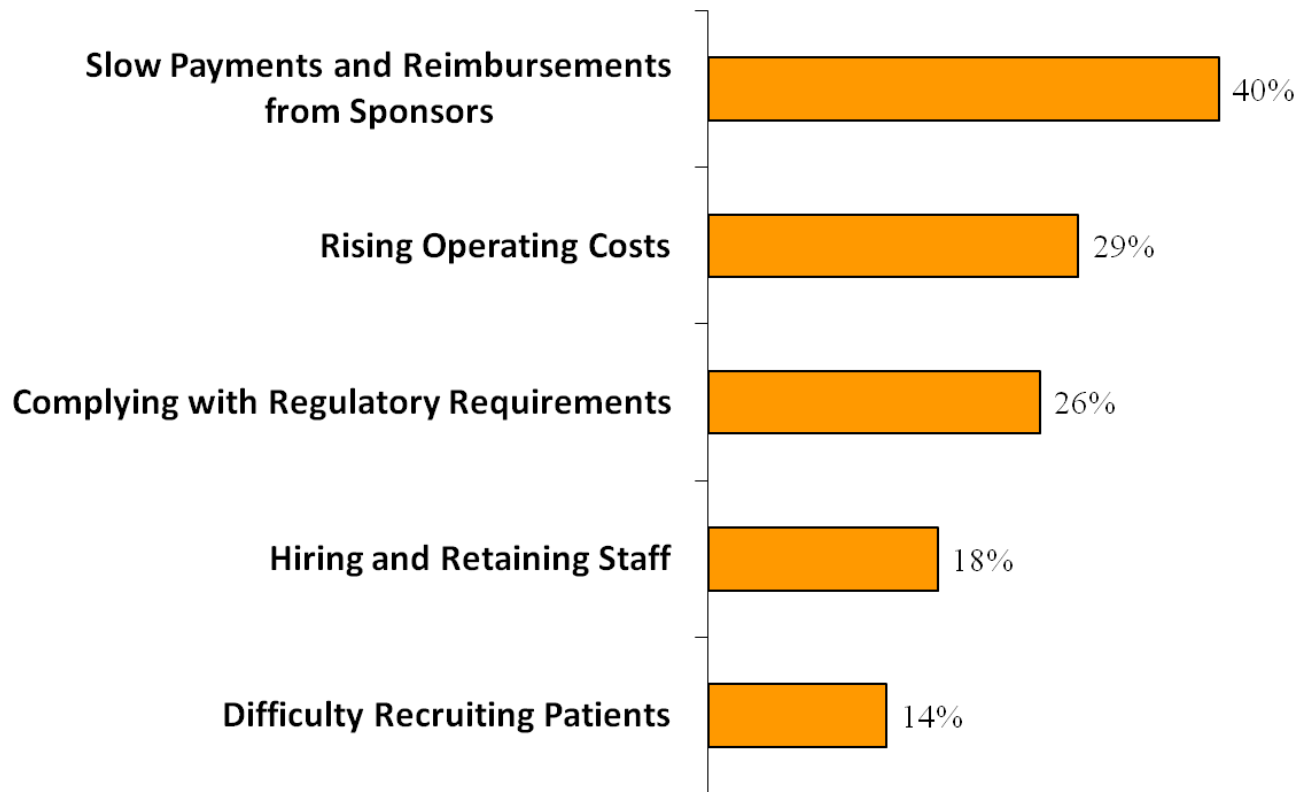
U.S. Department of Health and Human Services
Food and Drug Administration





Top Investigative Site Operating Concerns

(Percent of Respondents)



Source: CenterWatch Survey of 347 Investigative Sites (2009), Ken Getz from Site Solutions Summit 2010



■ ■ ■ Illusion

1. An erroneous perception of reality.
2. Something, such as a fantastic plan or desire, that causes an erroneous belief or perception.



6 Steps of a Successful Site





Business Foundation

- Human Resource
 - **Training**
 - **DOR**
- Facility & Equipment
- Business Development & Marketing
- Quality & Compliance Program
- Finances
- Commitment

Business Foundation



First learn of the study – study decision for your site

- **Feasibility**
- Pre-site Visit
- Enrollment Considerations
- Conversion rate

Time spent on feasibility	Overall
<30 minute	10%
30-60 Minutes	31%
1-2 hours	20%
2-3 hours	19%
3+ hours	19%



Site Selection – Study Activation

Sites that have less than 1 months expenses

GR	325K or <	325- 775K	775K- 1.7M	1.7M+
	29%	31%	16%	42%

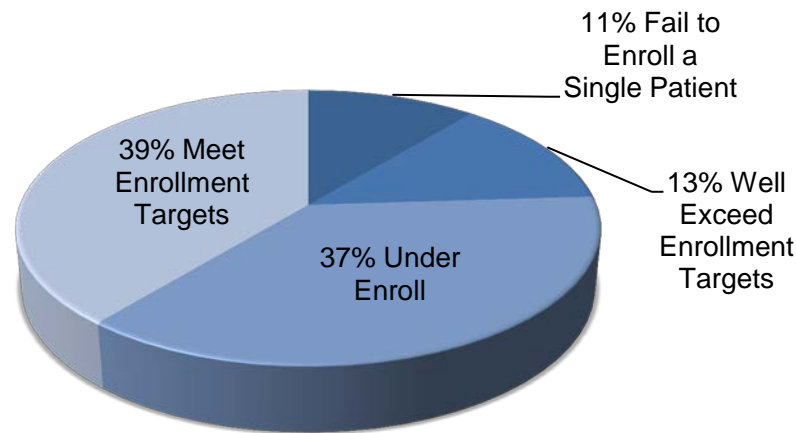
- **Budget & Contract**
- Regulatory Submission
- **Recruitment Plan**
- Training
- PI Meeting
- **Source Document Development**
- Equipment/Supplies
- **IP Management**



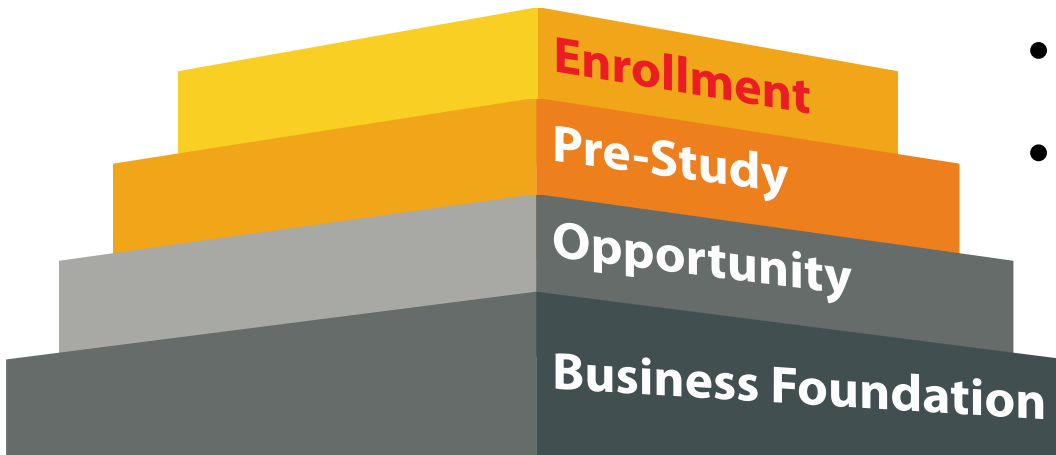
■ ■ ■ Perception vs. Site's Reality

	Sponsors & CROs # of hours spent	Sites # of hours spent
PI meeting (in person or on web)	9.2	16
Study related training	4.3	6
GCP training – for your study	1.3	24.5
Source Document Development	6.4	13
Screening charts for potential subjects	7.3	25

Site Activation – Study Enrollment Ends

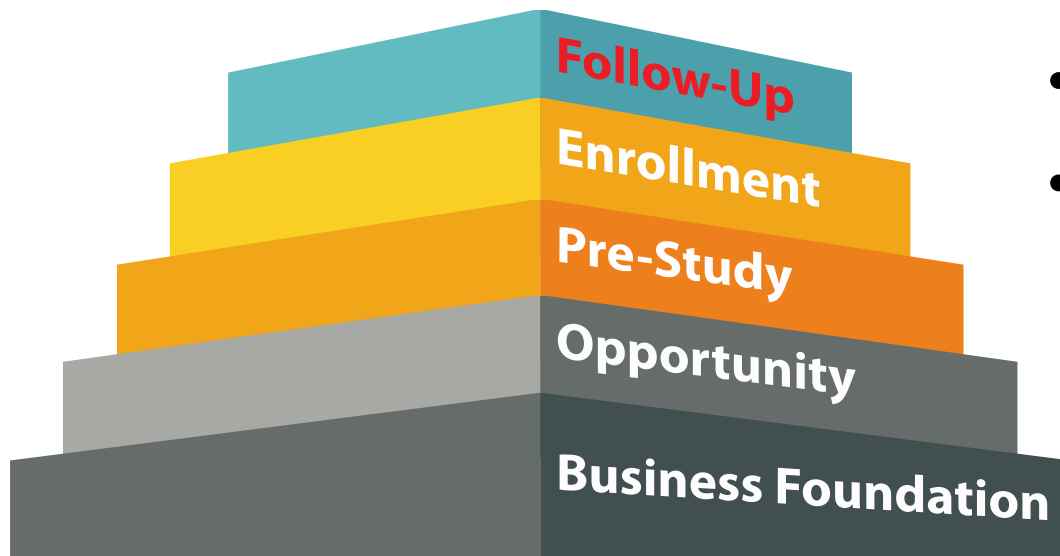


- **Screening**
- **Consenting**
- Randomization
- Retention
- **Data Management**
- Control of
 - Supplies/Inventory
 - **IP**
 - Regulatory Management





LPFV – LPLV



- **Retention**
- **Data Management**
- Control of Inventory
- **Control of IP**
- Regulatory Management



LPLV - Study Close Our Visit



- **Data Management**
- Control/Return of Inventory/IP
- **Regulatory Close Out**
- Achieved

If we're all seeing the same things, understanding what it takes to be a successful & trusted partner is easy. *But, we don't all see things the same way.*

