



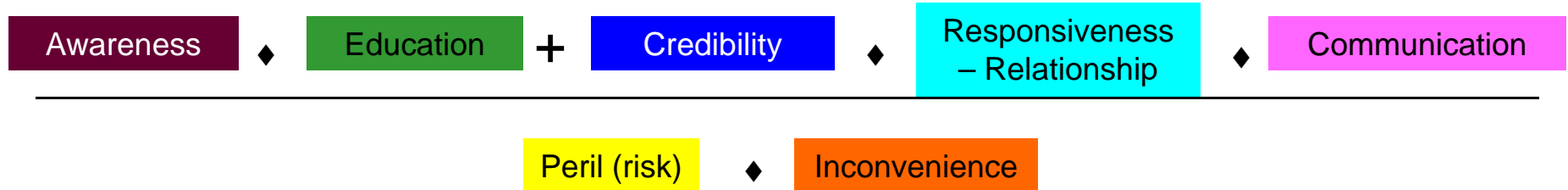
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PATIENT RECRUITMENT PLANNING GUIDE



From the Patient Perspective

Clinical Trial Participation
is a function of



Clinical Trials Participation is a Function of:

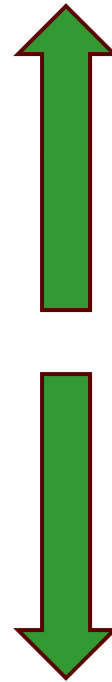
- The subject's awareness of the study opportunity
- The extent to which the subject is well educated and informed about clinical trials in general and about the specifics of the given clinical trial
- The credibility of the site staff conducting the trial
- The strength of the relationship the site has with the subject and how responsive they are to subject inquires and needs
- The nature and frequency of communication between the subject and key site staff

- Divided by:
 - The amount of risk or peril and inconvenience associated with the study

- Any time you increase the numerator, your chances of success increase, but it is especially important to do even more "AE + CRC" when "PI" increases, in order to key the study in a reasonable balance. When the level of Peril or Risk and Inconvenience is high, the more difficult it will be to ensure successful study participation.

To Increase the Likelihood of Site and Patient Participation We Must

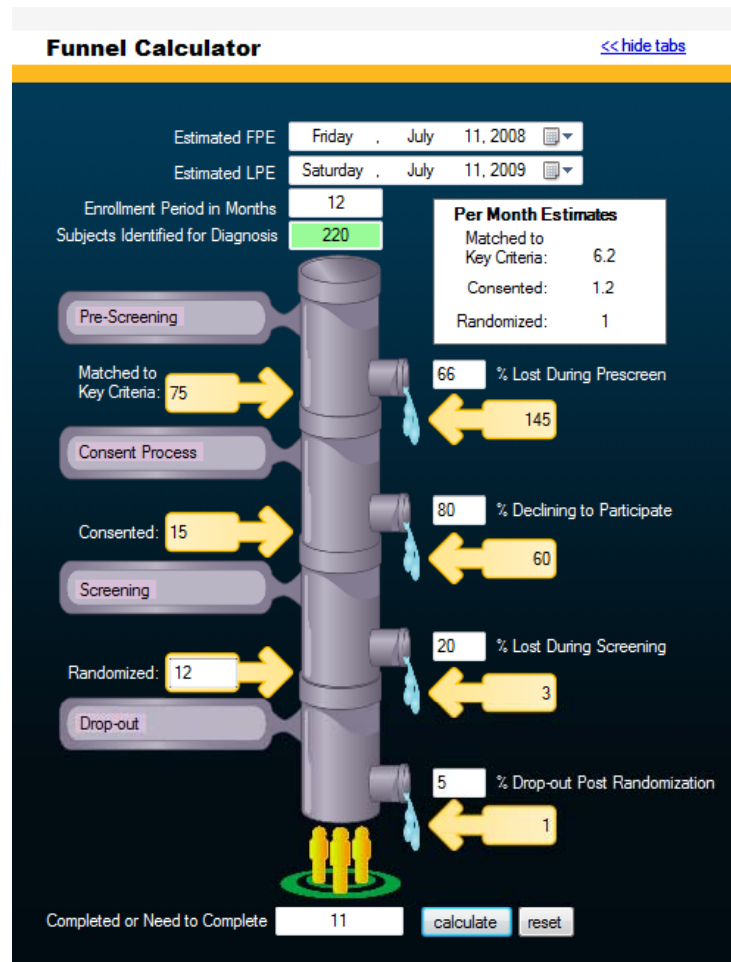
$$\text{CTP} = \frac{\text{AE} + \text{CRC}}{\text{PI}}$$



Increase the numerator

Decrease the denominator
(where feasible)

The “Leaky Pipe” Analysis



- “Filling the Funnel” requires a lot of “A and E” and Some “C”
- “Managing the Leaks” requires a lot of “CRC”, some “E” and a reduction of “PI” where possible

Does your Recruitment Plan Account for all the Common Patient Questions?

Category	Common Patient Questions
A wareness	Do I even know about the opportunity?
E ducation	What is a clinical trial?
	Where can / should I go for more info?
	Who else should I talk to?
	What will my personal physician say about this?
	What happens after the study? Will I still be treated?
C redibility	Who should I trust?
	Do I trust the people at the site?
	What's the experience of the site?
	How will my privacy be protected?
	How informed are the site personnel?

Does your Recruitment Plan Account for all the Common Patient Questions?

Category	Common Patient Questions
R esponsiveness / R esponsiveness	How often do I hear from the site?
	Will I be able to reach the investigator / staff quickly if I have an issue?
	Do I sense that the site staff have a genuine interest in my well being?
	Do I have an established relationship with the site?
C ommunication	Do I understand what they are saying?
	Is there someone on staff who speaks my language?

Does your Recruitment Plan Account for all the Common Patient Questions?

Category	Common Patient Questions
P eril (risk)	What are the risks / benefits?
	How invasive are the procedures?
	What happens if something bad happens to me?
I nconvenience	Can I get to the site?
	How much will it cost to get to the site?
	When is the site open?
	Will I be able to make my appointments and not interfere with my work schedule?
	How long will the study go for?
	How many visits are there?
	How many procedures are there?
	What compensation is available?
	Will my insurance cover the costs?

Building Study Awareness

Category	Questions and Sponsors / Sites Should Ask During the Study Planning and Implementation Process
Awareness	Who is the target audience that needs to be aware of the study opportunity (e.g., site, public, referring physicians, patient advocacy groups, etc.)
	Who is a potential source of patients?
	What will be done to identify and attract patients to the study?
	What are the most cost-effective ways to build and maintain awareness of the study?
	What methods / materials will be needed?
	What strategies and tactics will be used?
	What approvals are needed for the materials?
	Who will develop these?
	How much will it cost?
	When will they be developed?
	Who will implement the strategies? When?
	What methods and means are needed to maintain visibility of the study at the site and keep the study “front of mind” with site personnel?

Education

Category	Questions and Sponsors / Sites Should Ask During the Study Planning and Implementation Process
Education	Who needs to be educated about which aspects of the study? Patients? Family Members? Other Staff Members and Referring Physicians? Primary Care Physicians? Emergency Department Staff?
	What tools / materials are needed to supplement the informed consent document?
	What training is needed for site personnel? For patients and families? For potential “influencers”?
	What are the most effective means of training these individuals?
	What questions will the patient have about the study?
	How well are site personnel prepared to respond to participant questions?

Credibility

Category	Questions and Sponsors / Sites Should Ask During the Study Planning and Implementation Process
Credibility	Who at the site is best prepared to present the study and respond to patient / family questions?
	What should the site prepare to put their experience into context?
	Are all staff members (including “front line” personnel) aware of the study and know who to refer the patient to for specific questions?

Responsiveness - Relationships

Category	Questions and Sponsors / Sites Should Ask During the Study Planning and Implementation Process
Responsive- ness / Relationships	Does the site have clearly established processes and contact information for patient questions?
	Is the site adequately staffed and prepared to respond within 24 hours to patient questions?
	Are site personnel well versed in customer service skills and do they incorporate these principles into their operating procedures?

Communication

Category	Questions and Sponsors / Sites Should Ask During the Study Planning and Implementation Process
Communication	Does the site have (or have access to) multi-lingual staff?
	Are all site personnel trained in appropriate cultural competence skills and sensitivities?
	Are all study related materials presented in understandable language and translated as appropriate?
	Does site have a systematic process for “handing” the patient from one site professional to another (e.g., warm or cold transfer between the PI office to lab technician)?
	Does the site have a systematic patient communications plan (and adequate materials) for managing patient / family / influencer communication over the course of the trial?
	Does the study team have a systematic patient communications plan (and adequate materials) for managing site communication over the course of the trial?

Peril (risk)

Category	Questions and Sponsors / Sites Should Ask During the Study Planning and Implementation Process
Peril (risk)	Are study risks / potential benefits put into appropriate context and presented by most appropriate individual (s) at the site?
	Is a qualified physician available at all times?
	Is there a process in place to ensure the patient has access to the most current information in a real-time fashion?
	Does site provide patient with emergency contact cards / information?

Inconvenience

Category	Questions and Sponsors / Sites Should Ask During the Study Planning and Implementation Process
Inconvenience	What are the barriers to study participation? How will we overcome these? What strategies and tactics will be used? (apply a similar sequence of questions as noted in the awareness section)
	How much flexibility is the site willing and able to offer in terms of office hours?
	Does the budget adequately allow for site and patient / family inconvenience (e.g., on-call staff for the site, patient transportation reimbursement, etc.)
	Is subject compensation adequate? Have all ethical considerations regarding subject compensation been explored and considered?
	Does site have a user-friendly way to help patients get to the site navigate throughout the site (e.g., map, escorts, van service, wheelchair assistance, etc.)
	Has site proactively researched the insurance reimbursement process so they are comfortable putting research costs into appropriate context?