

CLINICAL  
& TRANSLATIONAL  
SCIENCE INSTITUTE

**Principles of Recruitment:  
Human Subject Recruitment  
Strategies, Tactics & Resources**

***“No one is as interested or  
enthusiastic about your study  
as you are.”***

**Your mission.....you choose to accept it....  
stimulate interest....enthusiasm...**

## Feasibility Assessments

### Multiple approaches

### Establish and manage relationships

- Know your recruitment sites/partners
- Know your subjects

## Feasibility Assessment

- Site
  - Potentially eligible patients?
  - Interested in study?
  - Experience with research participation?
  - Perception about study risk
  - How much can they realistically support recruitment efforts?
    - Administrative burden
  - Training needs?
  - What has been your/others' experience with that site?

## Feasibility Assessment

- Subject Recruitment and Retention
  - What has worked (and not worked) in the past?
  - What rates are realistic?
    - Track and use your data
    - Evidence from the literature
  - New opportunities
    - Future research registries
    - EMR
    - Social media

# From the Patient Perspective

Clinical Trial Participation  
is a function of

Awareness



Education

+

Credibility



Responsiveness  
– Relationship



Communication

Peril (risk)



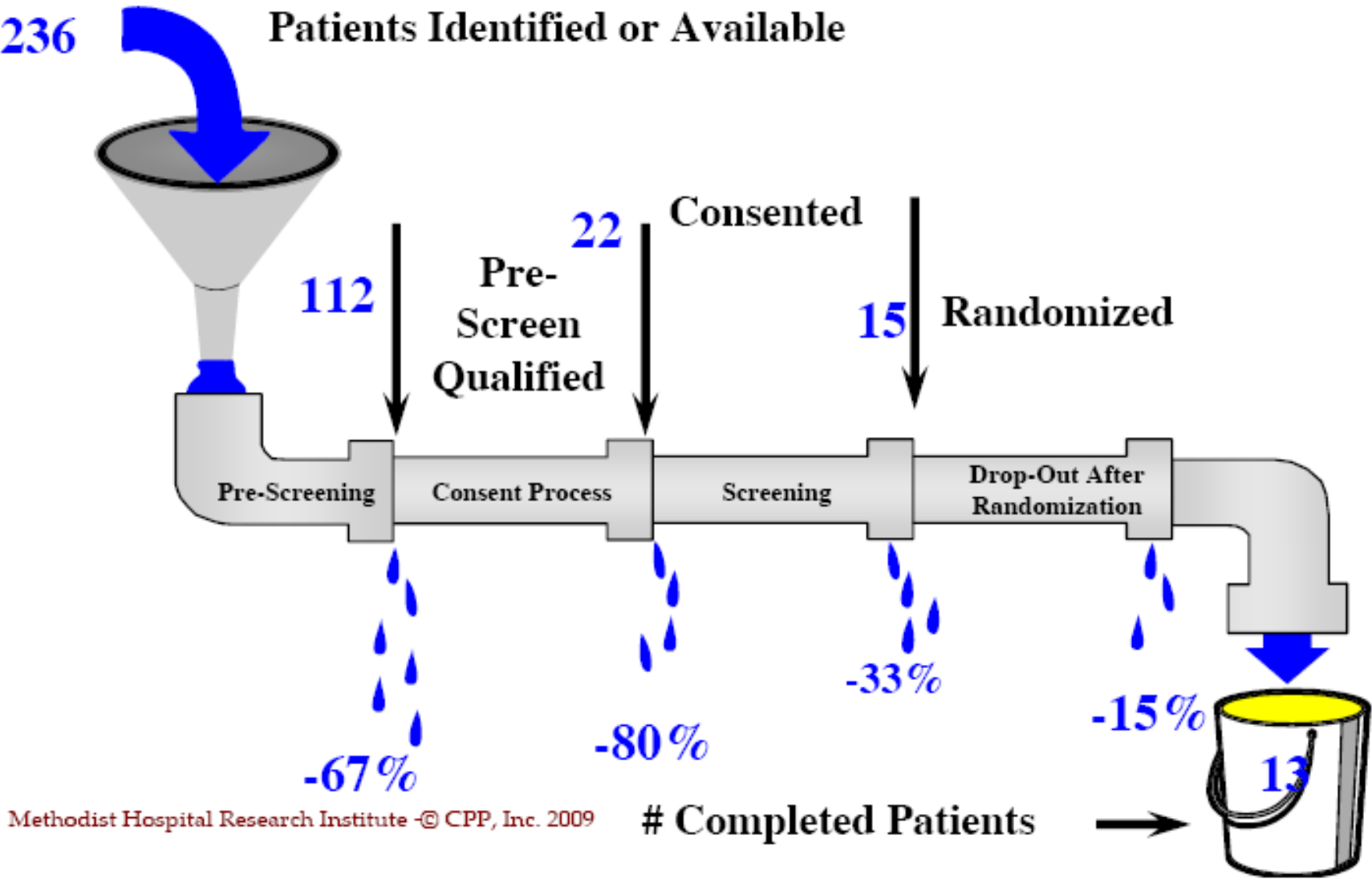
Inconvenience

## Multiple approaches

- Have a PLAN!
- Best and worst case enrollment scenarios?
  - Expect attrition
- One method is not enough
  - Track success from each source
  - Have alternative sites ready
  - ResearchMatch.org
- Track your costs
  - Time is money
    - What is the cost of screening vs. cost of losing someone at the point of consent or post consent

# Systematically Estimating Enrollment:

The "Leaky Pipe" Analysis





Estimated FPE  ,  11, 2008

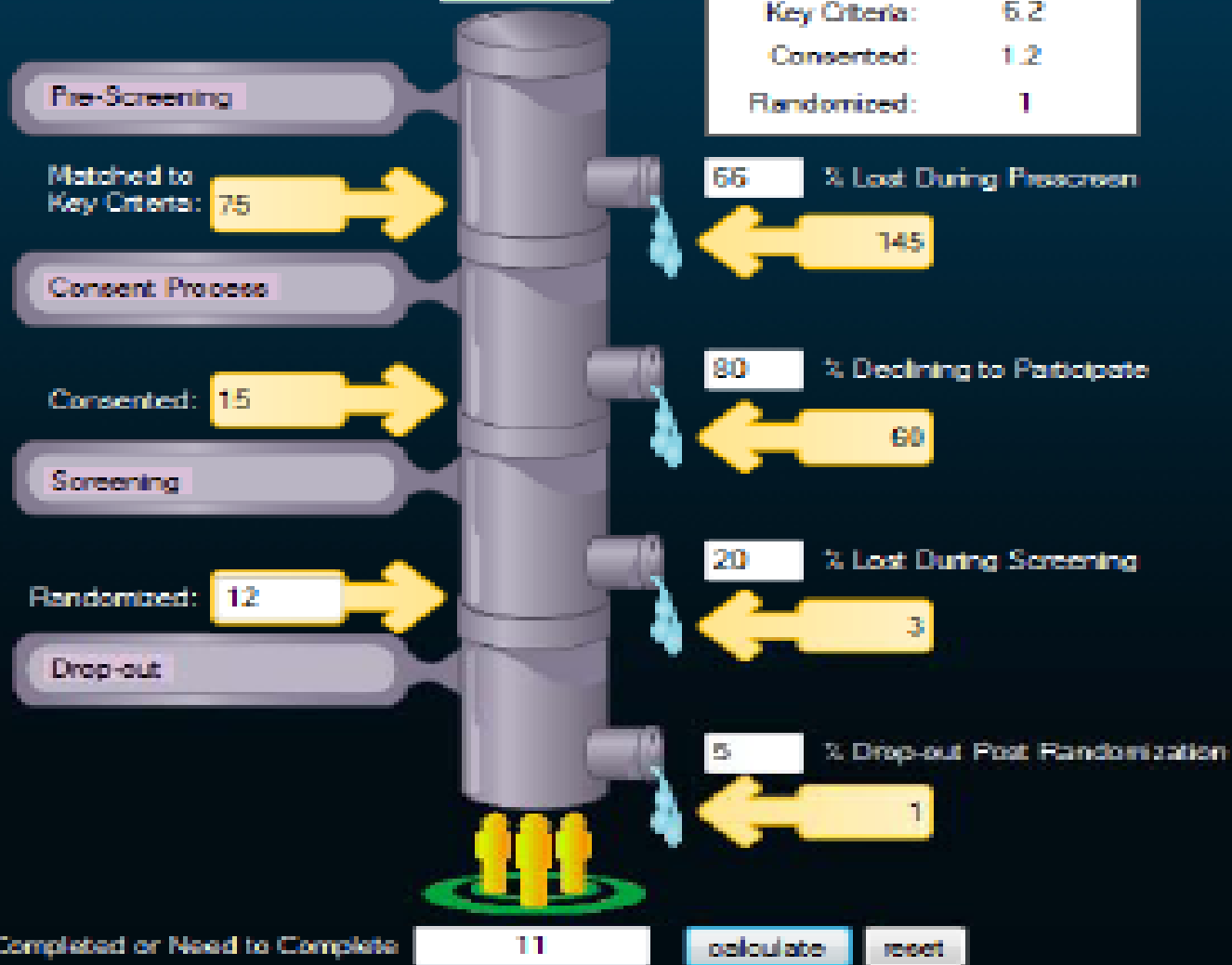
Estimated LPE  ,  11, 2009

Enrollment Period in Months

Subjects Identified for Diagnosis

### Per Month Estimates

Matched to Key Criteria: 6.2  
Consented: 1.2  
Randomized: 1



<b>"Top Down" Funnel Calculations</b>		
Funnel Parameters and Stages	Values	
Enrollment Period (months)	9	
# of Sites	20	
# Patients at a Given Site with Diagnosis or # Patients Available Across All Sites	200	<b>START HERE</b>
% Lost During Pre-Screening	0.33	
% Decline to Participate	0.8	
% Lost During Screening	0.65	
% Drop-out Post Randomization	0.25	
Funnel Calculations	Projected Values	
Patients Available	200	
Pre-Screen Qualified	134	
Consented (Enrolled)	27	
Randomized	9	
Completed	7	
# Enrolled / Month	3	
Per Site Estimates (approximate)	Overall Targets	Monthly Estimates
# That Will Need to Be Identified	10.0	1.1
# That Will Need to Be Consented	1.3	0.1
# That Will Need to Be Randomized	0.5	0.1

Reverse or "Bottom Up" Funnel Calculations		
Funnel Parameters & Stages	Values	
Enrollment Period (months)	9	
# of Sites	20	
# Patients That Will Need to Be Identified	768	
% Lost During Pre-Screening	0.33	
% Decline to Participate	0.8	
% Lost During Screening	0.65	
% Drop-out Post Randomization	0.25	
Funnel Calculations	Projected Values	
Patients That Need to Be Identified	768	
Pre-Screen Qualified	514	
Consented (Enrolled)	103	
Randomized	36	<b>START HERE</b>
Completed	27	
# Enrolled / Month	11	
Per Site Estimates (approximate)	Overall Targets	Monthly Estimates
# That Will Need to Be Identified	38.4	4.3
# That Will Need to Be Consented	5.1	0.6
# That Will Need to Be Randomized	1.8	0.2



## ESTIMATING HUMAN SUBJECT RECRUITMENT AND RETENTION

Potentially Eligible



ID as Pot Eligible



Referred



Screened



Eligible



Consented



Participated



Completed

5000    community estimate

1000    identified through MD/other

790    79% of identified were referred

630    20% of referred unable to contact

311    50% of screened not eligible

222    30% of eligible will not consent

201    10% who consent will not participate

100    only 50% complete study

## Recruitment Funnel

	TOTAL						
	Month 1	Month 2	Month 3	Month 4	Totals	% LOST	% of REFERRED
Referred	90	105	95	75	365		
Screened	55	50	55	35	195	47%	53%
Eligible	24	31	41	28	124	36%	34%
Consented	20	25	27	19	91	27%	25%
Participated	16	23	23	14	76	16%	21%
Completed	14	18	17	15	64	16%	18%

## Set up data collection such that you can answer

- where in the pipeline you are or are not having success – where is the fall off
- if you are recruiting from different sites what is the pattern from different sites
- if multiple enrollers are involved what is the pattern across enrollers
- if recruitment happens different days of the week or in different time periods (e.g. days, evenings) what is the pattern across these different periods
- if you need certain sub-groups, what is the pattern of their recruitment and retention

## Individual Level Tracking

	Date	Name	Cont act info (pho ne)	Age	Race	No cont act	How referred				Eligibility				Elig?
							(site)				Meets Eligibility Criteria				
							DrA	DrB	Clinic A	Clinic B	A	B	C	D	
1		AS		24	W	X	X								N
2		SD		26	W			X			y	y	y	y	Y
3		DF		56	W				X			y			N
4		FG		77	B			X			y	y	y	Y	N
5		RT		34	W				X				y	y	N
6		TY		65	W		X				y	y	y	y	Y
7		YU		75	W					X			y		N



## Individual Level Tracking

#	Elig?	Reason			Cons? Date	Study #	Enroller	Completed/Dropped	Date	Why Dropped
		MR	Tx	Oth						
1	N						n/a			
2	Y	X					n/a			
3	N						n/a			
4	N						n/a			
5	N						n/a			
6	Y				1/5/2011		D	2/10/11	Unable to get to appointment	
7	N						n/a			

## Individual Level Tracking

Time	Agree to talk	Interested	Eligible	Consented
	<sub>1</sub> Yes <sub>0</sub> No	<sub>1</sub> Yes <sub>0</sub> No	a b c f g e or d DOB mom OK? _____ DOB infant OK? _____	<sub>1</sub> Yes <sub>0</sub> No If not why:
	<sub>1</sub> Yes <sub>0</sub> No	<sub>1</sub> Yes <sub>0</sub> No	a b c f g e or d DOB mom OK? _____ DOB infant OK? _____	<sub>1</sub> Yes <sub>0</sub> No If not why:
	<sub>1</sub> Yes <sub>0</sub> No	<sub>1</sub> Yes <sub>0</sub> No	a b c f g e or d DOB mom OK? _____ DOB infant OK? _____	<sub>1</sub> Yes <sub>0</sub> No If not why:

## Relationship Management

### Know your recruitment sites/partners

- What are their barriers/facilitators
  - Is everyone on board
  - Be visible/follow-up
  - Appreciate them
- 
- <http://www.clinicalperformancepartners.com/download-able-tools-templates.php>

## Relationship Management

### Know your (potential) subjects

- Do they even know about the study
- What are their participation barriers/facilitators
  - Logistic, attitudinal
  - Do they understand the study requirements
- Appreciate them

Address:		City:	State:	Zip:
Contact Info:  <input type="checkbox"/> Home: <input type="checkbox"/> Work: <input checked="" type="checkbox"/> OK to contact * Best # to reach patient <input type="checkbox"/> Cell: <input type="checkbox"/> email:		Best Time to Reach Patient:	Best Appointment Days / Times:	
Languages:		Occupation:	Employment Status: <input type="checkbox"/> unemployed <input type="checkbox"/> retired <input type="checkbox"/> full time <input type="checkbox"/> part time	
Spouse / Significant Other:		Children / Grand Children:		
Favorite Foods:		Pets:		
Hobbies / Sports / Interests:		Books / Movies / Music:		
Other Notes:		Anniversary / Significant Milestones:		

**Important Information Needs / Expectations:**

- Disease management
- Treatment alternatives
- Clinical trials – general
- Clinical trials – study specific info / updates
- Updates on labs / diagnostic reports or health status  
\_\_\_\_\_ to self \_\_\_\_\_ to PCP
- See MD at each visit
- No waiting time in clinic
- Pager / 24-hour availability to staff
- Frequent contact by staff
- Appointment reminders
- Recognition
- Other:

**Primary Motivators:**

- Inadequate response to current treatment
- Side effects from current treatment
- Low cost medical treatment
- Altruistic reasons
- Seeking more information about disease / disease management
- Other:

**Logistical Considerations:**

- Transportation challenges
- Flexible / convenient appointment times
- Financial challenges
- Insurance issues
- Other:

## UR CTSI ResearchHelp

- <http://www.urmc.rochester.edu/ctsi/research-help/>
- Practice Based Research Network
- Recruitment and Retention Resources
  - Consultation
  - Branded materials

## Accrualnet

- <https://accrualnet.cancer.gov/>

## Clinical performance partners

- <http://www.clinicalperformancepartners.com/downloadable-tools-templates.php>

## Center for Information and Study on Clinical Research Participation

- <http://www.ciscrp.org/>

## *Summary*

### **Feasibility Assessments**

**A must.....**

**including both overall and site specific**

**Multiple approaches**

**Have a plan....assume problems.....attrition**

**Establish and manage relationships**

**Site/partner and subject**