



Realistic Recruitment, Enrollment & Retention Planning

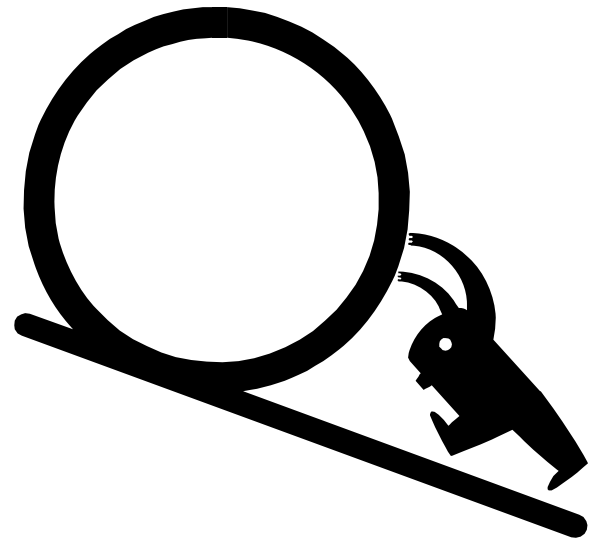


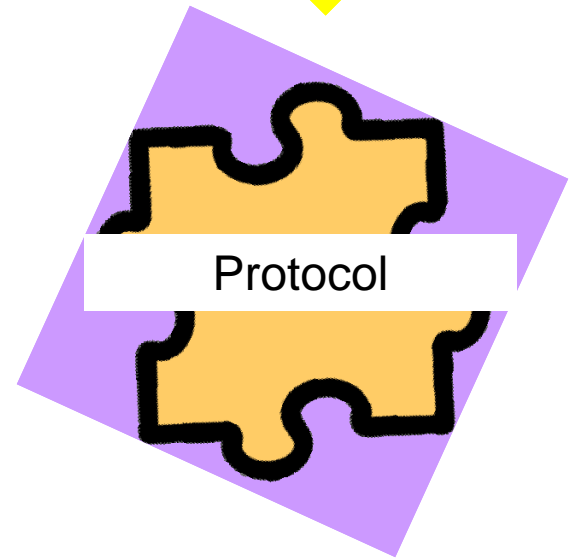
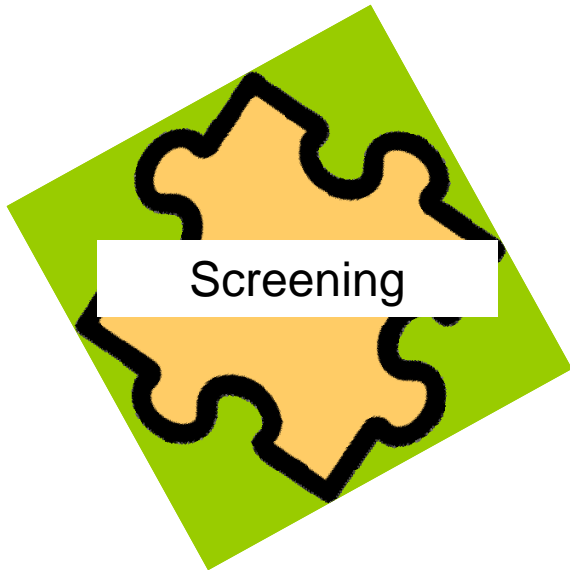
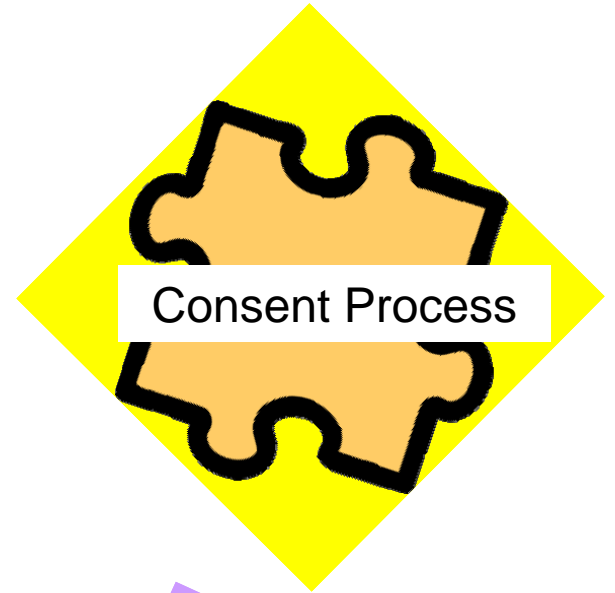
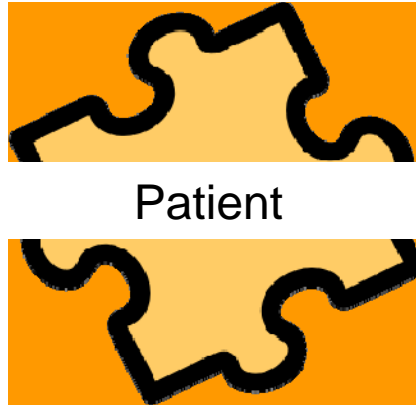
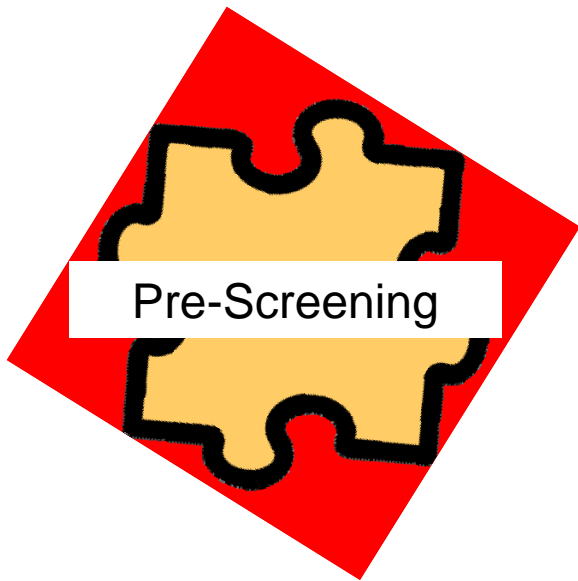
Clinical Trial Activity in Canada

- Clinical trials in Canada: decrease by 12% per year:
 - Rising cost and deficits
 - Recruiting patient issues
 - Lengthy timelines and delays
 - Inefficient processes
 - Lack of time to complete the work, etc...

- Faculty of Health Sciences (Queen's, KGH, HDH, PC):
 - F08: 214 clinical trials
 - F11: 168 clinical trials
 - F08: \$9.5 Million
 - F11: \$4.9 Million

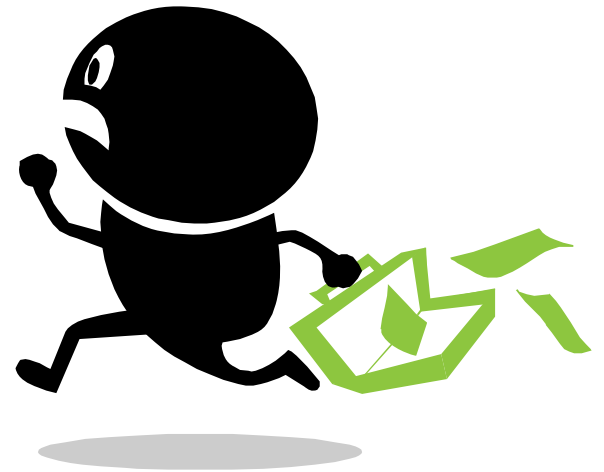
*Successful recruitment,
enrollment and retention of
participants for any clinical trial is
a challenge...*





***Patient recruitment, enrollment, and retention
represents a critical bottleneck in clinical research...***

The majority of clinical trials are delayed due to low enrollment... resulting not only delays in publication, lost revenue, but also delays in availability of potential marketable drugs and devices to patients.



Less than 20% of ALL sites actually deliver what they say they are going to deliver in terms of patient enrollment...

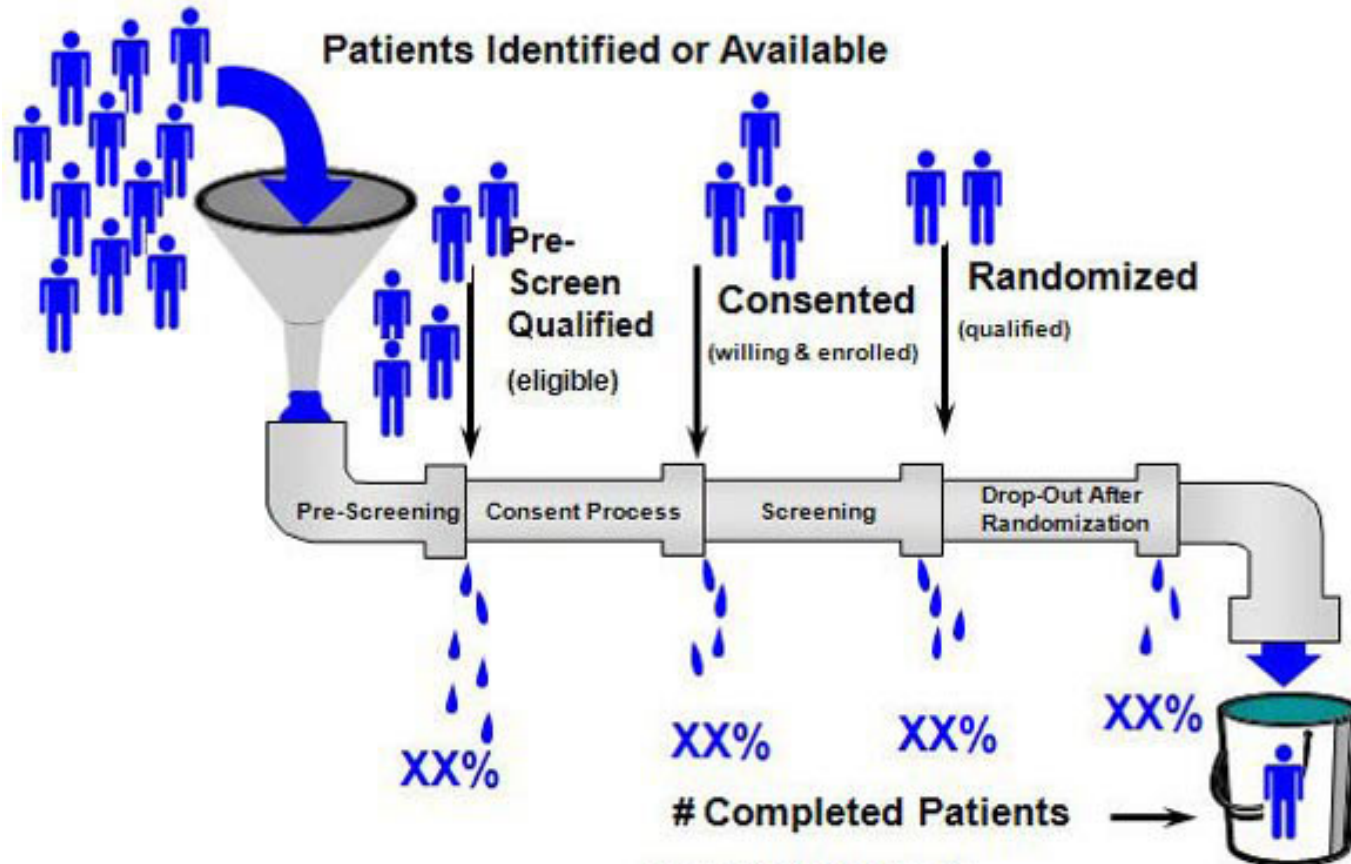


The recruitment, enrollment, and retention of subjects for your clinical trial is one of the most difficult and rate-limiting step for all studies...

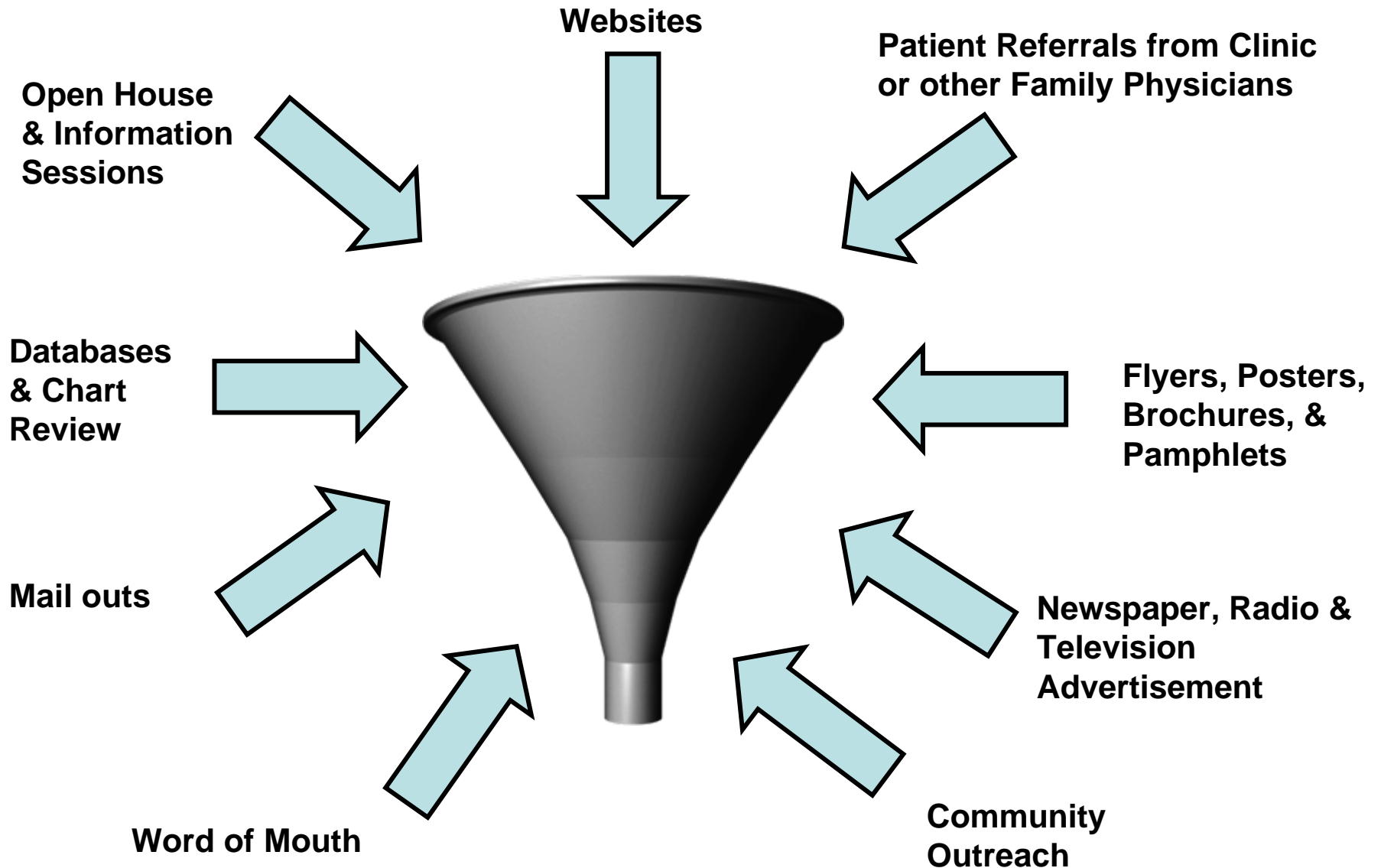


Understanding the PROCESS of Subject Participation

(The "Leaky Pipe" Analogy)

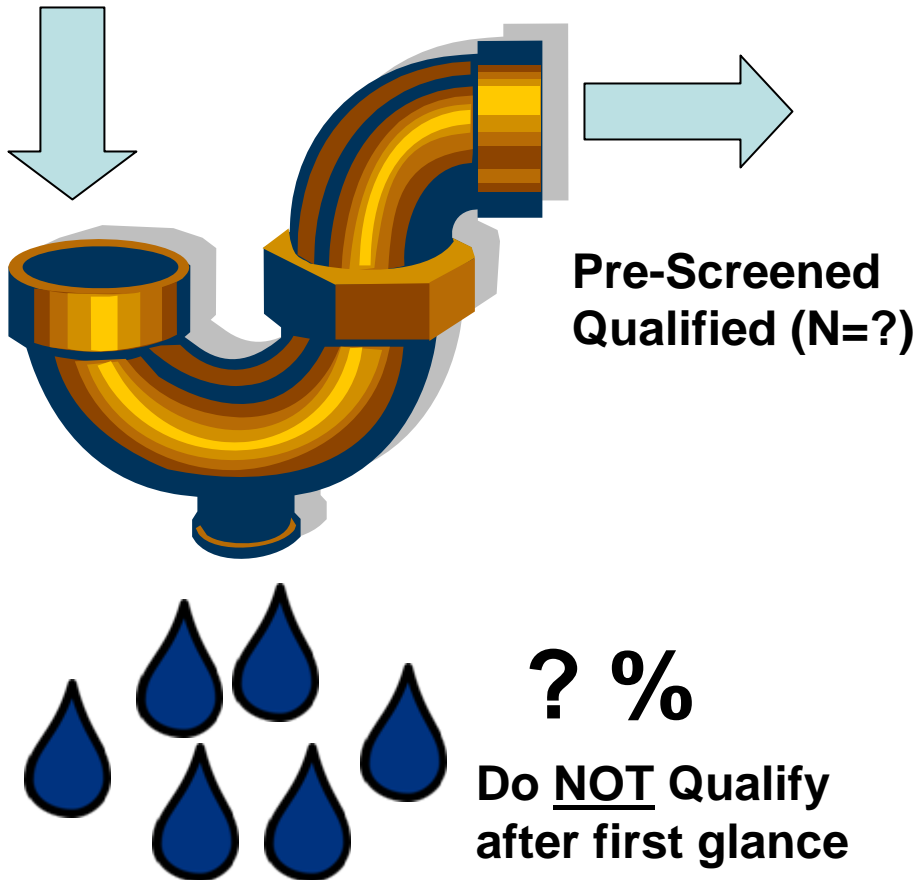


What Does it Take to Fill the Funnel?



Enrollment Planning: Pre-Screening

Potential Patient Population (N=?)

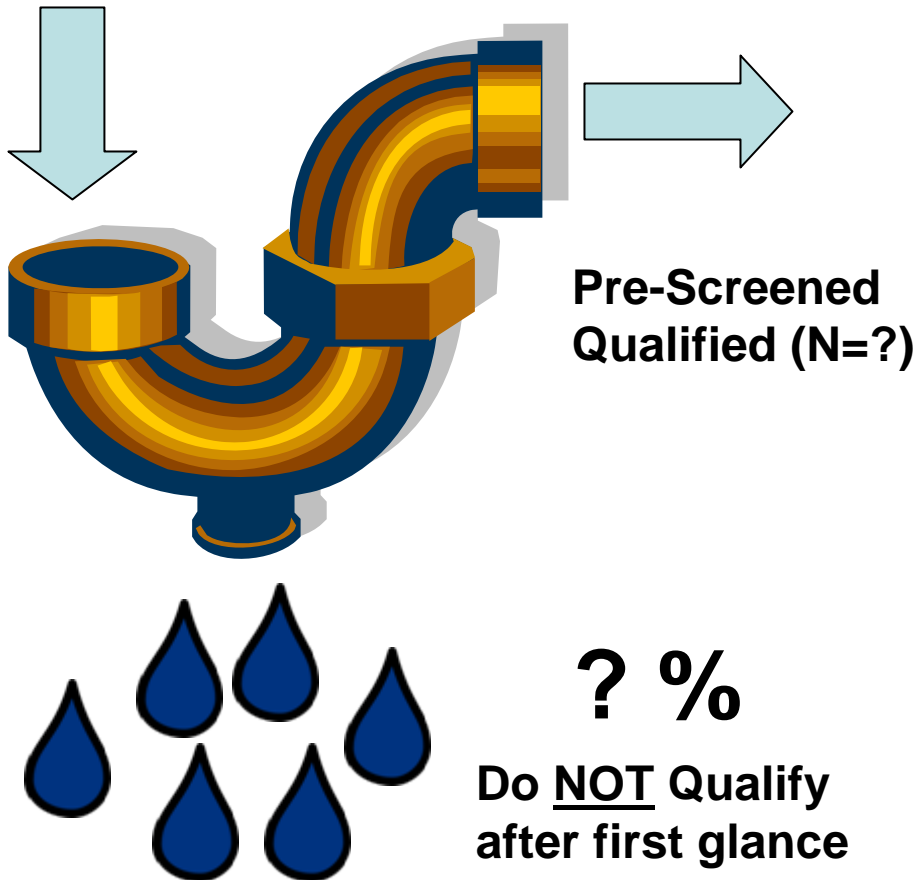


- Review your Protocol:

- *What is the patient population required?*
 - Does this population exist in the Kingston and surrounding area?
 - What does this population really look like?
 - How are you going to reach this population?
- *What are the inclusion/exclusion criteria for the study?*
 - Are they realistic and meet your patient population?
- *What is the time length of study and what are the enrollment timelines?*
 - Have you considered the “Snowbird” or “Turtle” effect?
- *What are the demands on your patient population?*
 - Procedures involved, number of visits to lab, withdrawal of medication, transportation, etc...

Enrollment Planning: Pre-Screening

Potential Patient Population (N=?)



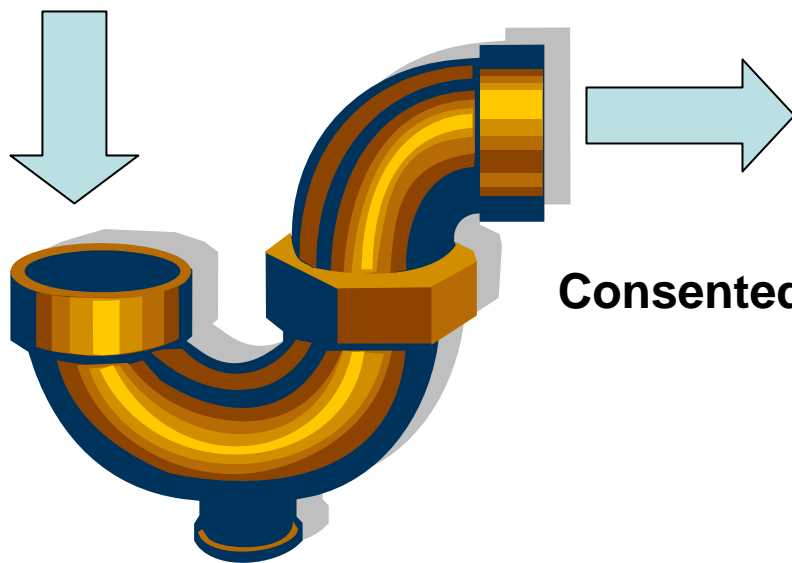
- Review your Personnel:

- *How many ongoing competing studies do you have on the go?*
 - *How will this study affect initiating new studies down the road?*
- *What is the time, effort and resources commitment of this study?*
 - *Do you have the resources (adequate space/equipment/staff) to carry out the study?*
 - *What is the availability of your research personnel or your availability to other hospital resources to carry out the study?*
 - *With industry-sponsored studies, you can expect that for every 1 hour of patient contact there is likely 3-4 hours of documentation (e.g. case-report forms, follow-up with test results) and follow-up from the sponsor?*
- *How often will the sponsor monitor the study?*

Enrollment Planning: Consent Process

How many can you realistically enroll?

Pre-Screened
Qualified (N=?)



Consented (N=?)



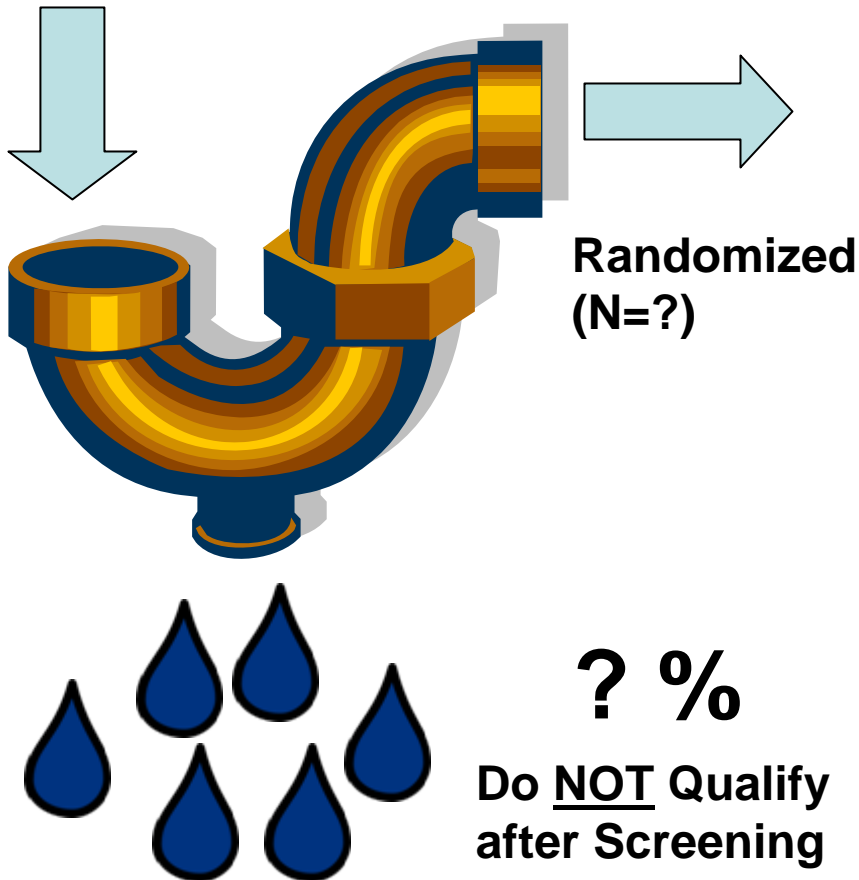
? %
Decide not to
Participate

- What Might Influence a Subject's Decision to Participate

- *Who will the patient encounter during the study?*
- *What are the hours of operation of the research lab?*
- *How many visits to the lab? How often? What time? How accessible?*
- *Reimbursement for parking and other study-related visits?*
- *Where to go between testing?*
- *What foreseeable benefit is there for the patient?*
- *Bad press/misconceptions regarding research participation (“guinea pig syndrome”) or bad prior experience.*
- *Beliefs that clinical trials are only for the terminally ill.*

Enrollment Planning: Screening

Consented (N=?)



Things You Can Not Control:

- *Laboratory test results;*
- *Diagnostic and imaging results;*
- *Physical examination findings;*
- *Medical history;*
- *Medication usage;*
- *Ability to complete test procedures;*
- *etc..*

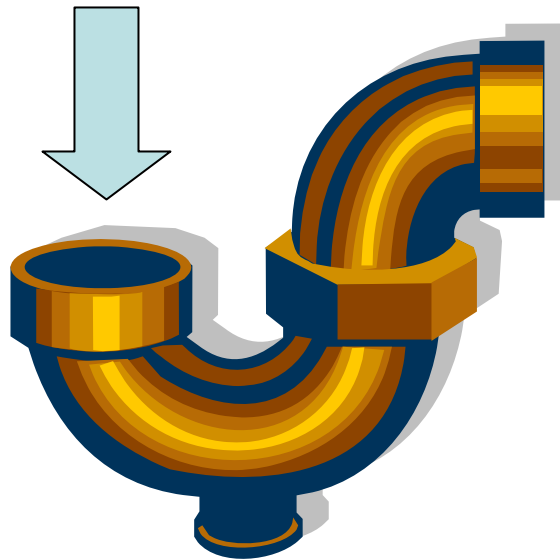
Things You Can Control:

- *Schedule study visits at a convenient time for subjects;*
- *Maintain close communication with subjects and their families;*
- *Ensuring subjects understand what their involvement will be;*
- *Return phone calls promptly;*
- ***Treating Study Volunteers as Customers.***

Enrollment Planning: Randomized

What does it take to keep subjects?

Randomized
(N=?)



Completed Study
(N=?)



? %
Drop out

Copyright 2003 by Randy Glasbergen.
www.glasbergen.com

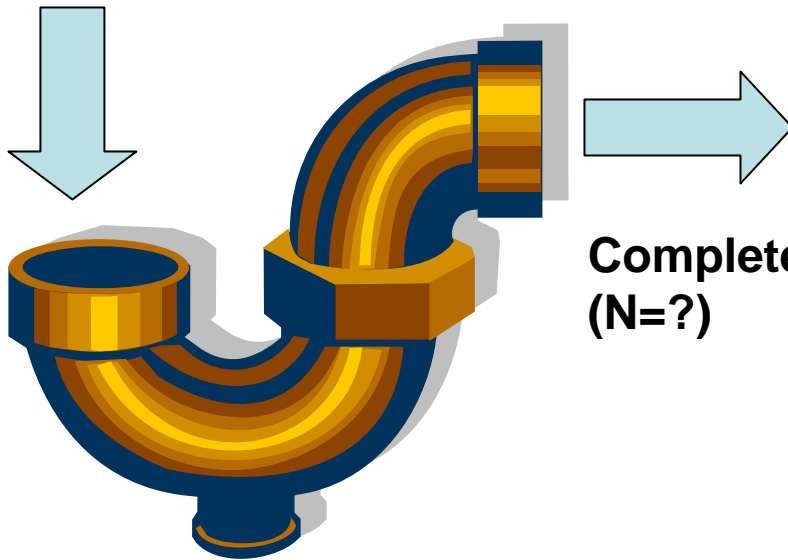


“What fits your busy schedule better, exercising one hour a day or being dead 24 hours a day?”

Enrollment Planning: Randomized

What does it take to keep subjects?

Randomized
(N=?)



Completed Study
(N=?)

? %
Drop out

- What do Subjects Want?

- Engaging staff:
 - “People friendly” individuals that they can have a connection with
 - “Putting the right staff in the right positions...”
 - Information about their health, medical condition, and the progress of the study.
 - Feel that they have someone to contact if they have questions or concerns.
 - Results sent to family physician.
- Feel appreciated and know that their time and contribution is valued:
 - Thank you notes.
 - Birthday cards.
 - Newsletters.
 - Final outcomes of the study.
 - Follow-up after the study.
- Visit reminder cards or telephone follow-up calls prior to next visit.
- Transportation or caregiver support.

Sometimes it is not about
filling the funnel...



...Sometimes it is about
managing our losses at various
stages of the study

Establish a Plan for Recruitment, Enrollment, and Retention

- Assess where your “*leaks/cracks*” are in regards recruitment, enrollment, and retention for studies.
- Identify the resources and materials needed to manage the “*leaks/cracks*” to support the recruitment, enrollment, and retention activities.
- Determine roles and responsibilities for implementing the plan.
- Track progress against the goals.
- Document successes
 - AVOID REINVENTING THE WHEEL!



IF IT ISN'T DOCUMENTED...



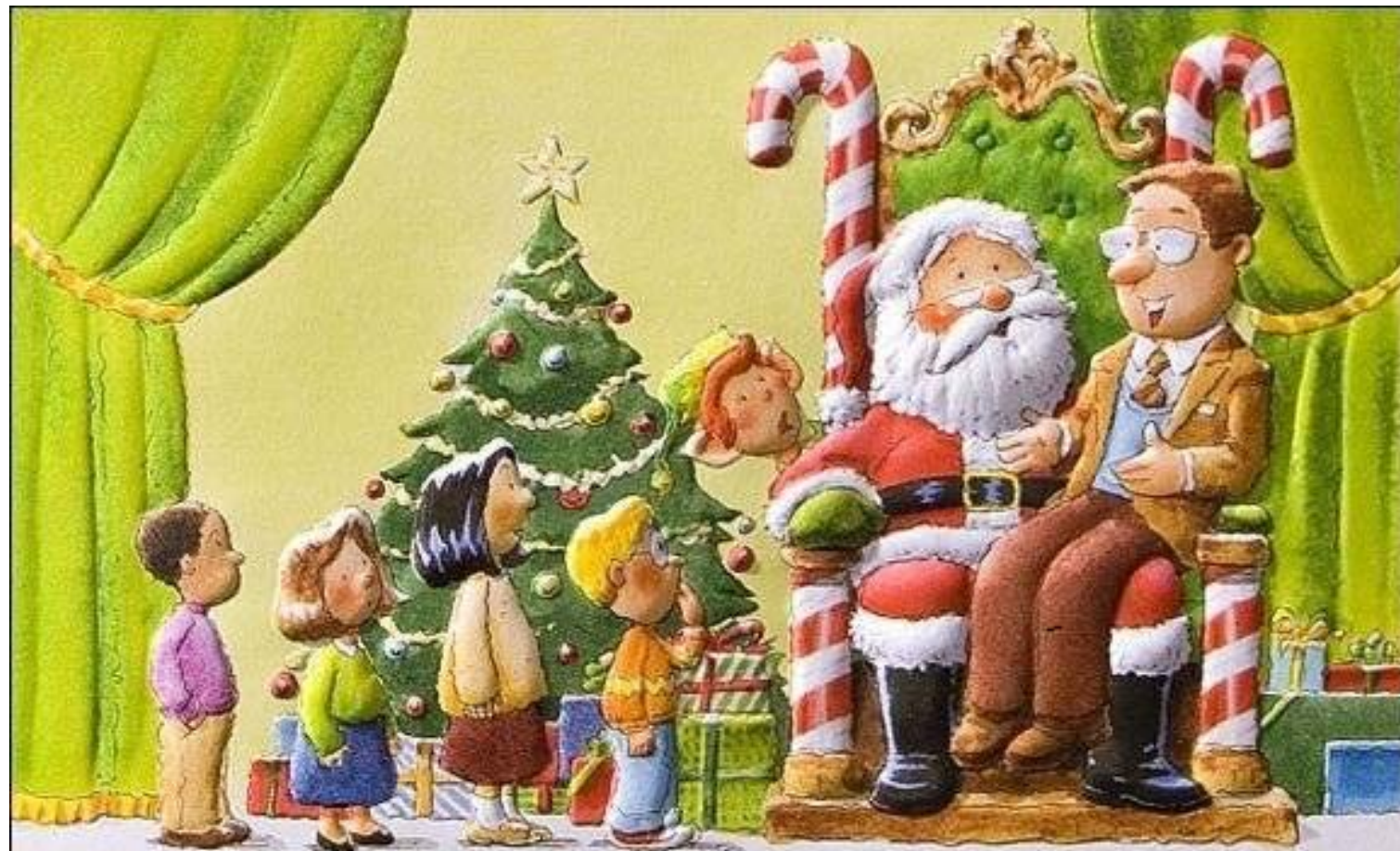
It won't get done!

Build the Referral Network

- Make a list of health care providers coming in contact with potential patients.
- Recruit them to a lunch and learn session about your research group.
- Ask for help.
- Keep them informed:
 - Study start date and close date
 - Enrollment status
 - Type of patient
- Thank them for helping.



Collaborate Early...



"...Lot of patients randomized for my studies, No queries, all visits and procedures done per protocol, and a trip to Bahamas after the study is finished. That's all I want, Santa!!"

Questions?

