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**Where Are all the Patients?  
Recruitment and Advertising  
for Clinical Trials  
or  
How to Make Your Numbers  
Without Losing Your Mind**

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NC TraCS Research Recruitment Director

# Learning Objectives

- Gain knowledge about the clinical research award and site selection process
- Discover how a good feasibility process will help you get studies that fit your patient population and how to avoid those that don't
- Learn how to target your recruitment efforts
- Leverage your resources to get more studies that are right for your research goals



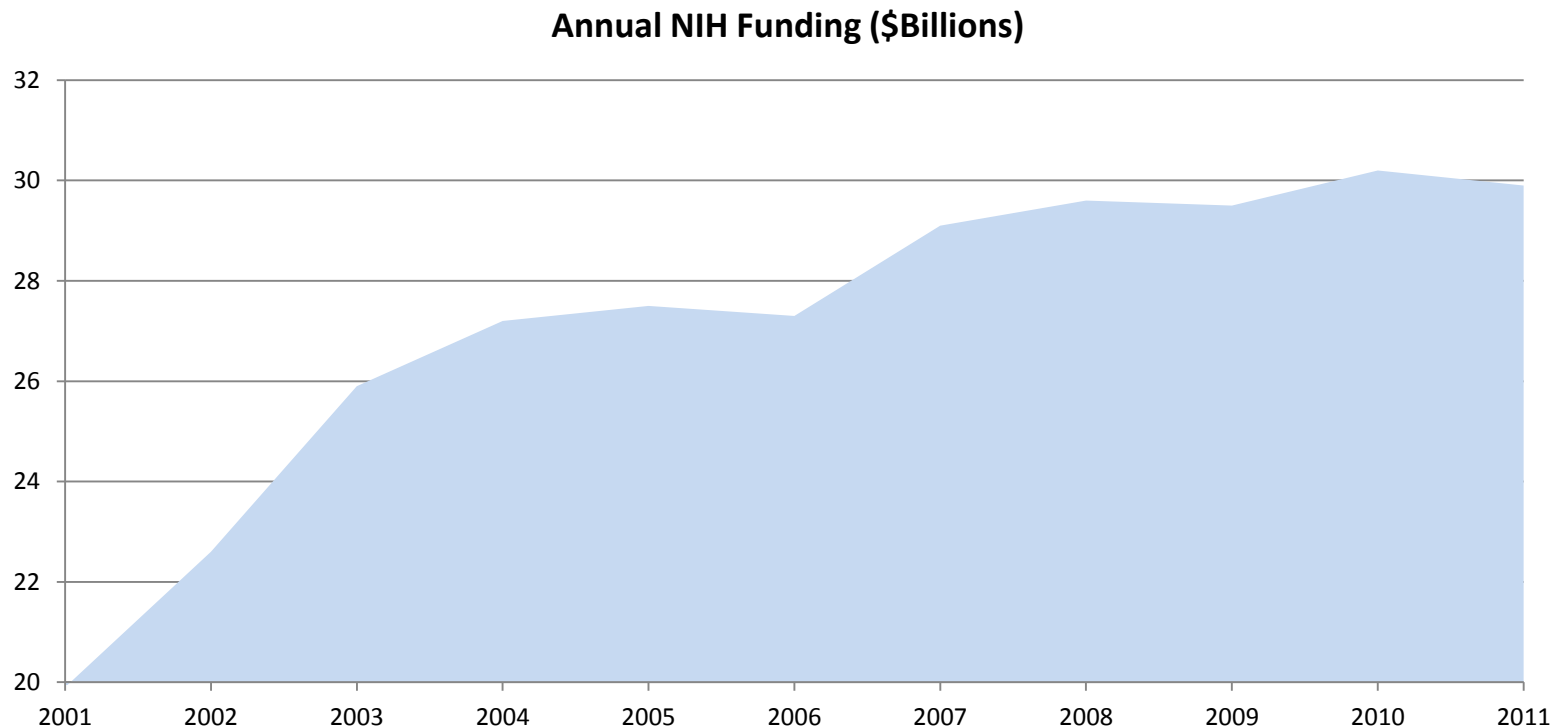
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# **CLINICAL RESEARCH AWARD AND SITE SELECTION PROCESS**

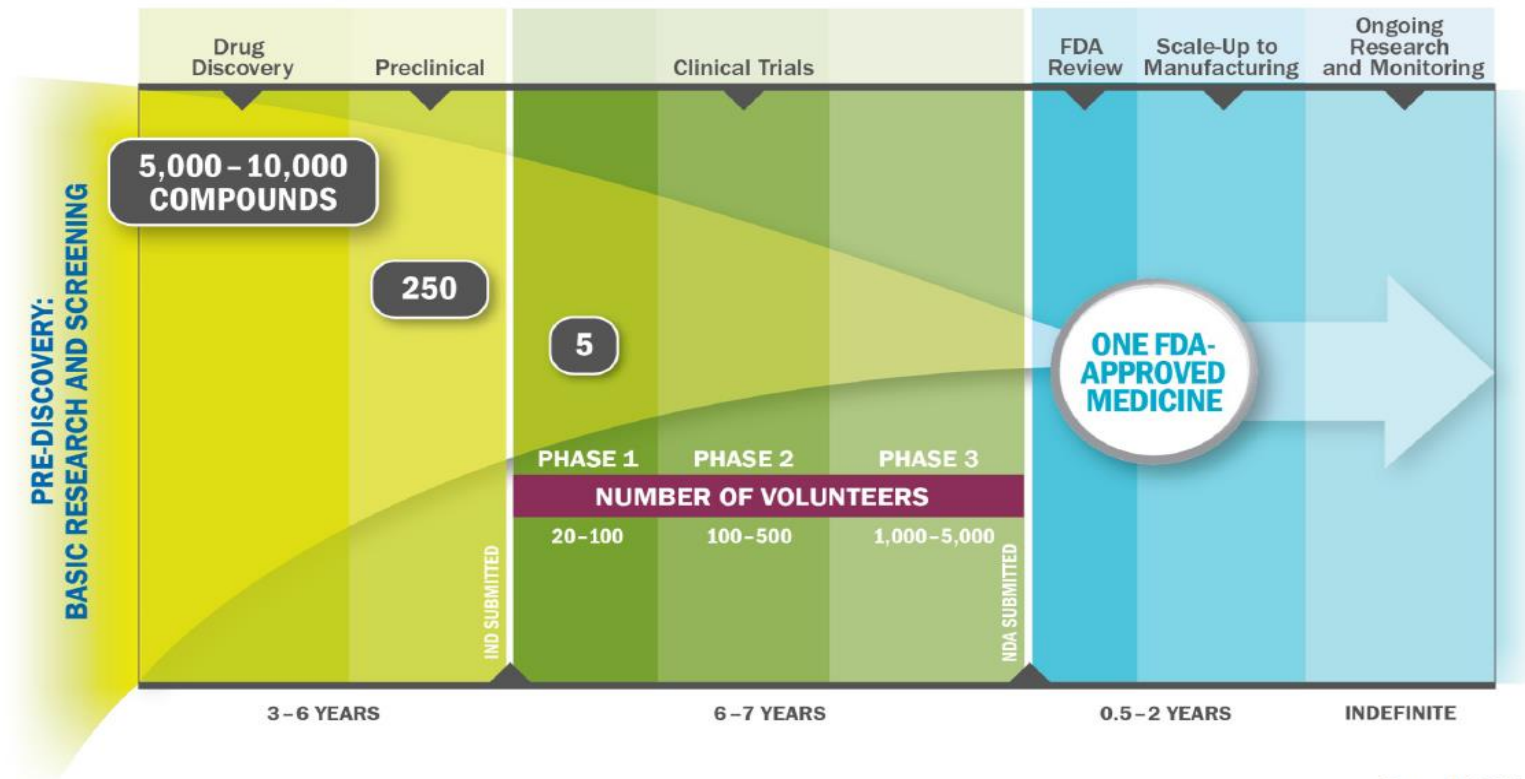
# Federal Funding of Research

- As the federal government and state/local governments experience more constrained budgets, resulting in fewer or lower research funding opportunities, the university must diversify funding sources.



# The Drug Research & Development Process

Developing a new medicine takes an average of 10–15 years.



Source: PhRMA<sup>4</sup>



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Slide courtesy of  
Steve Cornwell, Business Development Officer  
NC TraCS

# A glimpse inside the sponsor's world

## Job 1: FDA approval



The sponsor is funded by many individual investors who provide many millions of dollars to develop a drug. The patent on a drug lasts 17-20 years.



By the time clinical trials are ready to start, many patent years are already used up. Time is short to make money to pay off investors.

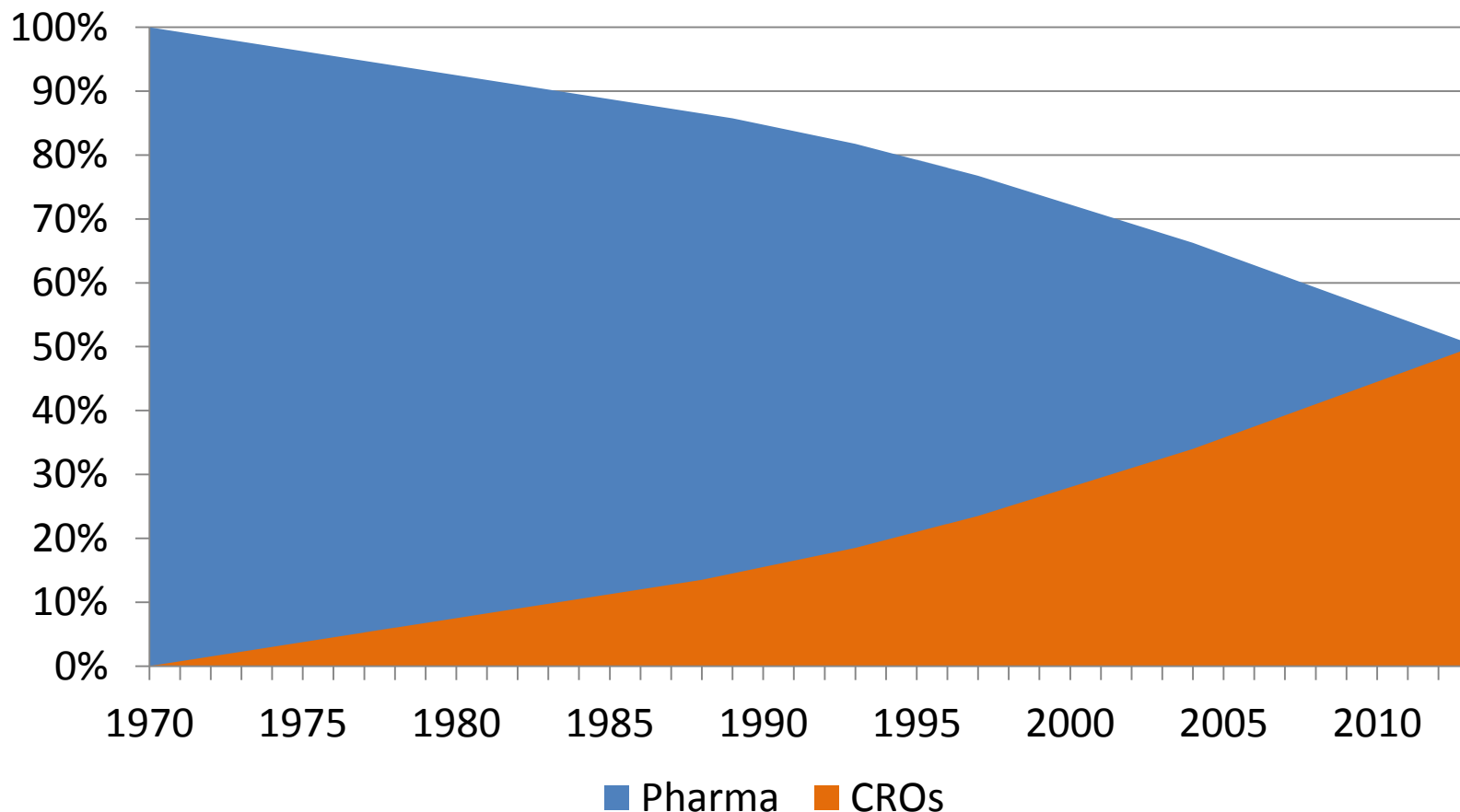


The sponsor needs sites to recruit subjects to generate clinical data. Clinical studies stand between financial success or huge losses. When subject recruitment lags the study is at risk. CROs are hired in part to mitigate subject recruitment risk.

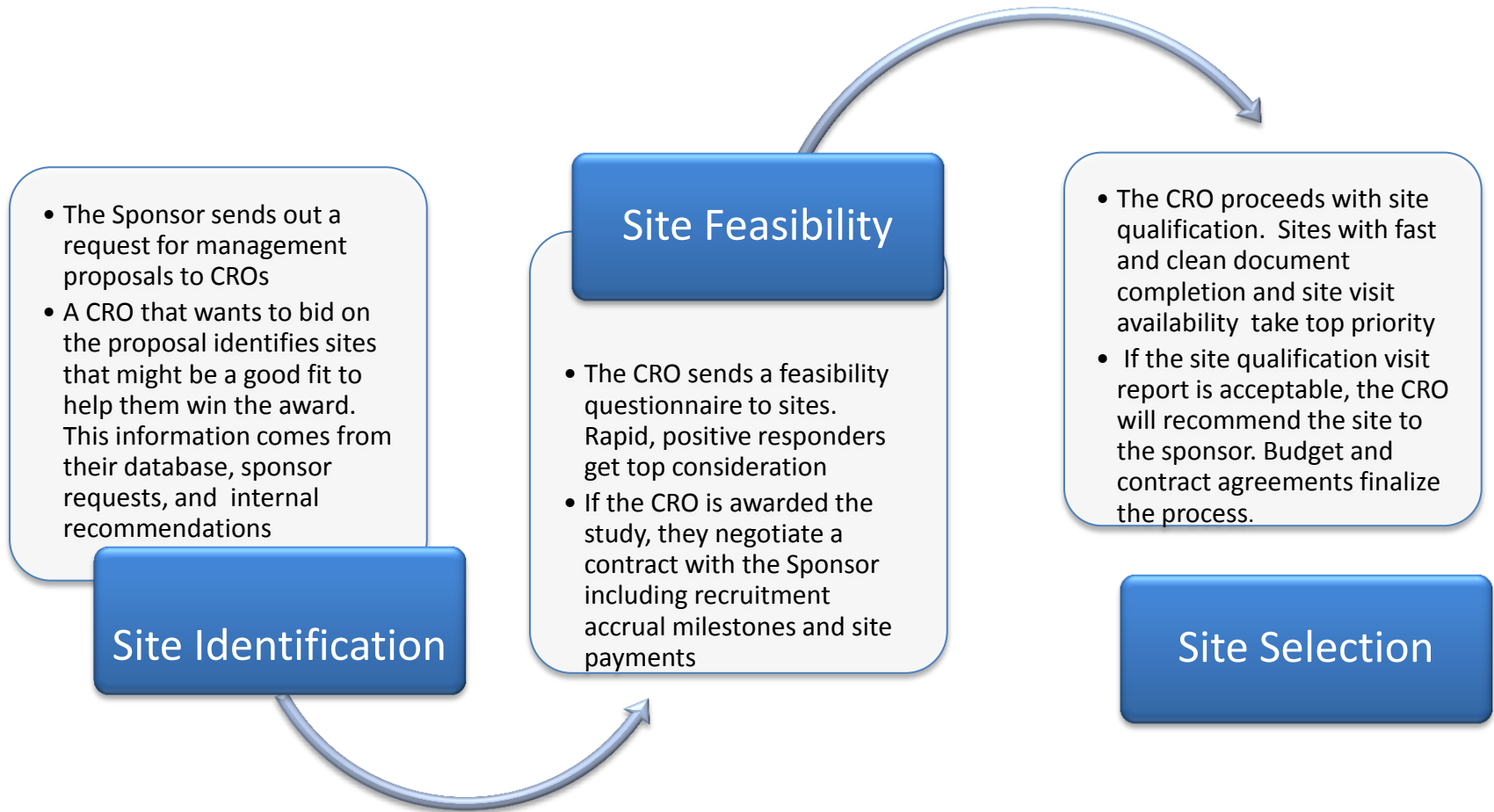


# Shifting Management of Clinical Trials

- CROs have continued to increase oversight of clinical trial conduct, accelerating in the last decade



# CROs and Site Selection



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# Good site characteristics -

## How does your site compare?

- Good location- less than 45 minutes from a major airport with reasonably priced hotels and restaurants nearby
- Proper equipment for the study in good working condition – scales; centrifuges; PFT equipment; etc.
- Secure pharmacy or on-site drug storage with 24/7 monitored temperatures
- If using the hospital pharmacy, ensure SOPs are in place for dispensing and storage of drug (drug will only be shipped to one address.)
- Easy access to site for patients- parking; public transportation or shuttles. (For on campus sites this is a challenge- how do you overcome it?)
- Additional rooms dedicated to research activities
  - storage of study supplies away from storage of clinic supplies
  - locked file cabinets with keys only available to study team



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# Good staff characteristics

- Good internal relationships – organized and busy but not overstressed
- Documented training of staff in research procedures
- Reliable full-time study coordinator with dedicated research time and availability to respond quickly to email and voicemail
- A PI that keeps up with what is going on and knows about any issues or SAEs



# How to get the attention of CROs

- Don't be afraid to market yourself!
  - Enter your site in each CRO's database
  - <http://www.quintiles.com/quintiles-investigators/>
  - Highlight your positive characteristics
  - Describe your recruitment success (in numbers!)
- Create a promotional brochure
- Create a pleasing website that is easy to navigate
- <http://uncdiabetes.org/>
- Make sure your studies are on clinicaltrials.gov



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# **BUILDING A FEASIBLE FEASIBILITY PROCESS**

# A typical clinical site feasibility process

1. Quickly review the draft protocol synopsis and I/E
2. Ballpark estimate # of subjects you can recruit
3. Run some queries in your patient database or do quick chart review to confirm
4. Identify a bunch of patients that might qualify
5. Respond optimistically to your feasibility questionnaire
6. Wait around for someone to contact you



# The CRO's idea of your feasibility process

- On a Friday, they send you a Feasibility Questionnaire
- It's up to 100 questions long and they ask that you respond within 48 hours to all 100 questions as they are all equally important
- You forward it to your feasibility response team that is standing by 24/7 to assist you



- The team runs reports from your comprehensive database that gives the exact data requested and fills in the questionnaire for you
- After a restful weekend, you return the completed questionnaire to the CRO on Monday morning



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# Other CRO site start up assumptions

- You can clear your calendar at any time for a site qualification visit
- You will have only minor modifications to the informed consent template, contract template or proposed budget
- Your entire team can attend the Investigator Meeting on short notice



# Your Actual Feasibility Obligations

- ✚ The investigator should be able to demonstrate
- ✚ (e.g., based on retrospective data)
- ✚ a potential for recruiting the required number of suitable subjects
- ✚ within the agreed recruitment period

*From the ICH Guidelines 4.2.1*





# Study feasibility reality checks

- Protocol design
- Available patient/volunteer population
- Recruitment barriers and timelines
- Recruitment advantages and any synergies
- Retention barriers and timelines
- Retention barriers and any synergies

# Adopt these feasibility practices

- Create a library of metrics for different patient populations and types of studies that you have experience in. This will save you a lot of time later.
- Write several recruitment success stories with details about challenges you overcame. Put these on your website and on sponsor site databases.
- As soon as you receive a feasibility questionnaire, send an email back right away to let the CRO know that you received it and are taking their proposal under consideration. This is good professional communication and will be much appreciated. If there will be a delay in reviewing it, let the CRO know when they can expect your response.
- Continue to follow up every few days. Set a reminder on your outlook calendar if needed.

# It's ok to decline poor fits

- If a study synopsis is not a good fit, respond right away and tell the CRO exactly why. Tell them what types of studies you are experienced in and would like to do in the future. Give them data and examples.
- If a study is poorly designed or will be too difficult to recruit and you are declining it, give the CRO clear feedback about the study. You are the expert and your comments are very valuable. It's possible that the protocol may be modified based on your comments.
- Find out if your site is an add-on site. If so, you may not realistically have time to get approval before recruitment is finished.



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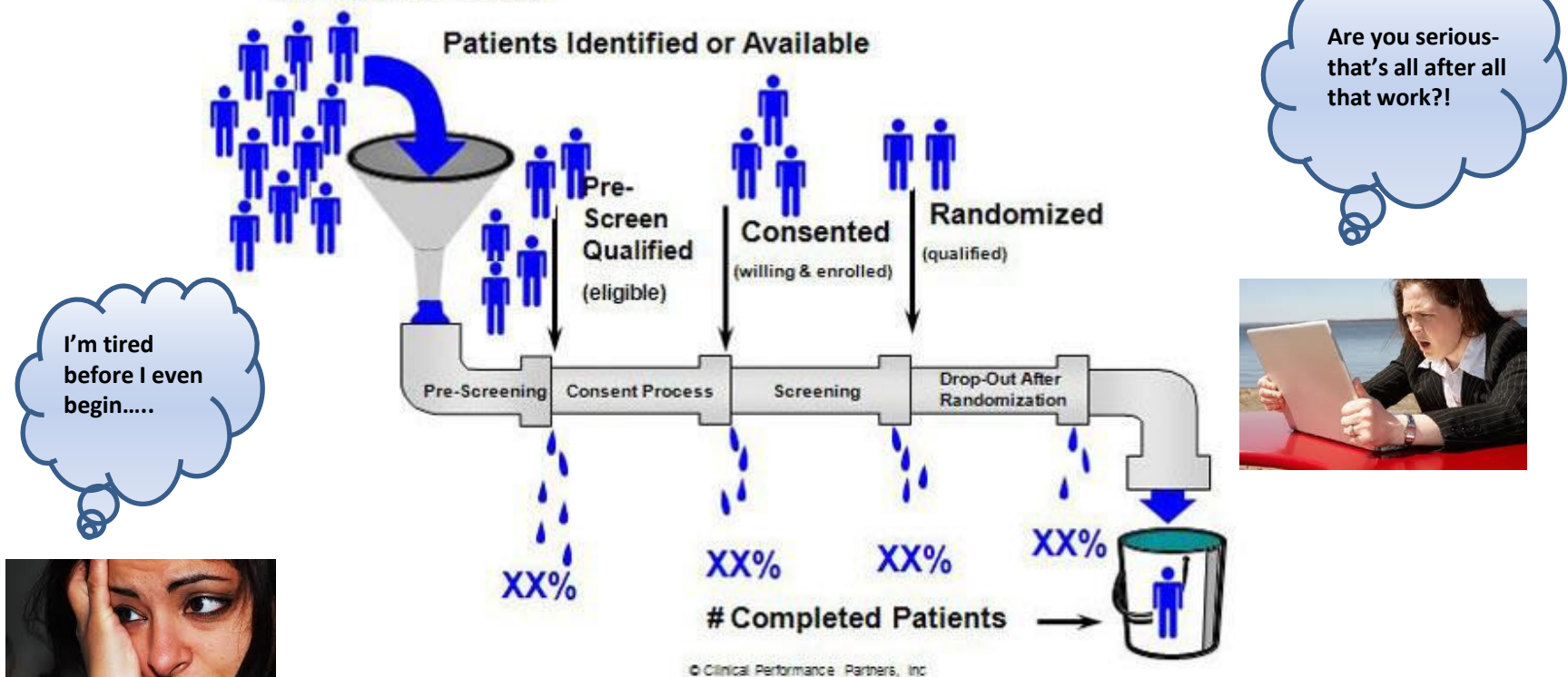
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# **THE TANGLED WEB OF RECRUITMENT AND RETENTION**

# Familiar Subject Recruitment Model

## “Leaky Pipe”

Understanding the PROCESS of Subject Participation  
(The “Leaky Pipe” Analogy)



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Model by Clinical  
Performance Partners, Inc

# Typical downward recruitment spiral

1. Screen a bunch of folks who don't actually qualify
2. End up with some patients who do qualify
3. Enroll a few but way less than you thought
4. Fall behind your recruitment timelines
5. Try to get some money to advertise
6. Run some ads or something
7. See #1
8. Stop answering calls from the CRA
9. Request site closure



# Are these your potential subjects?



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# Where are all the patients?

Look around you!



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# Use social marketing concepts to design your recruitment plan

- Social marketing is an approach where commercial marketing concepts are applied to public health initiatives to promote positive behavior changes
- By applying social marketing strategies to research, increased community engagement will translate into increased volunteer participation in research studies
- The key is to make research participation fun, easy and popular!



# Recruitment Plan

## Using Social Marketing Basics

- Know your audience(s)!
- What action(s) do you want your volunteer to take?
- What exchange is taking place?
- Who/what is your competition?
- Design your campaign with the 4Ps of Marketing (Product, Place, Price, Promotion)
- Develop an evaluation plan- identify risks and contingencies
- Make adjustments based on your evaluation results

# Retention Considerations

- How long are your recruitment timelines ?
- How long would the subjects need to be in the study?
- How many visits do you expect them to complete?
- Do you foresee any difficulties with subjects returning for visits?

# Keys to Recruitment Success

- Understand the clinical award process
- Characterize your patient and community population target audiences
- Determine realistic feasibility
- Create a SMART recruitment plan (specific, measurable, attainable, relevant, timely)
- Budget for recruitment contingencies
- Keep communication channels open



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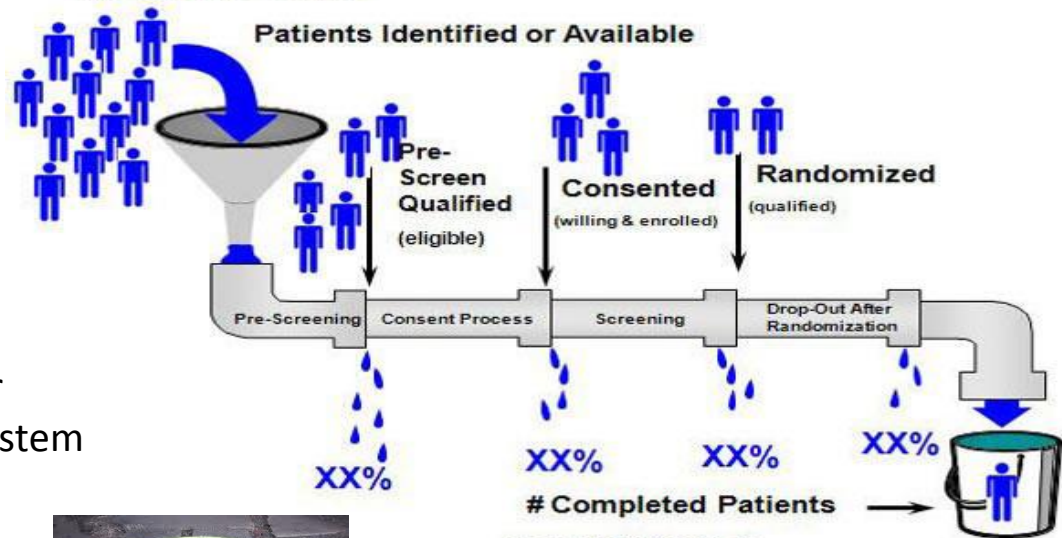
# **LEVERAGING YOUR RESOURCES**

# Go green!

## Result? Larger and More Diverse Volunteer Pool



### Understanding the PROCESS of Subject Participation (The "Leaky Pipe" Analogy)



UNC Volunteer  
Recruitment System

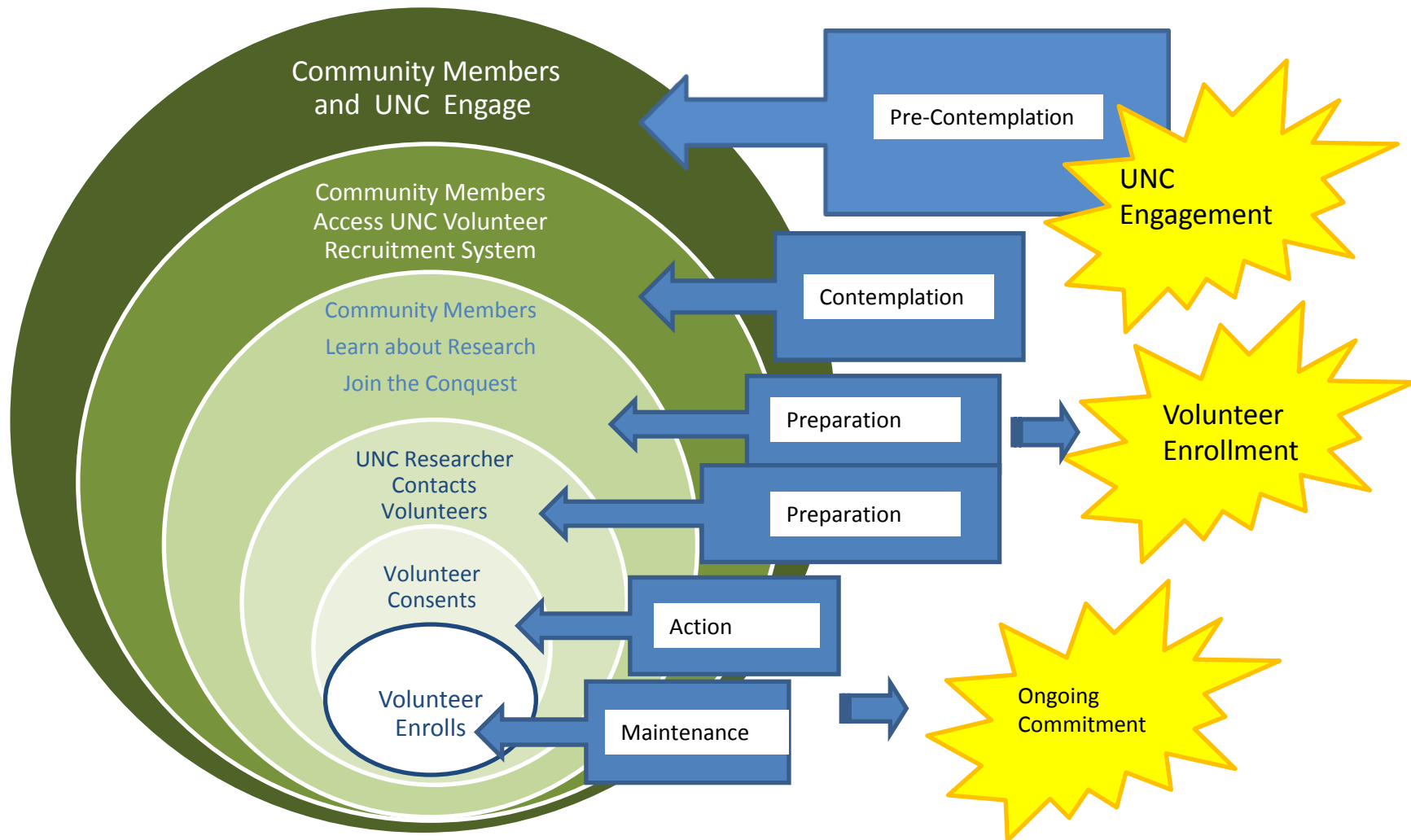


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# Community Integrated TraCS Research Recruitment

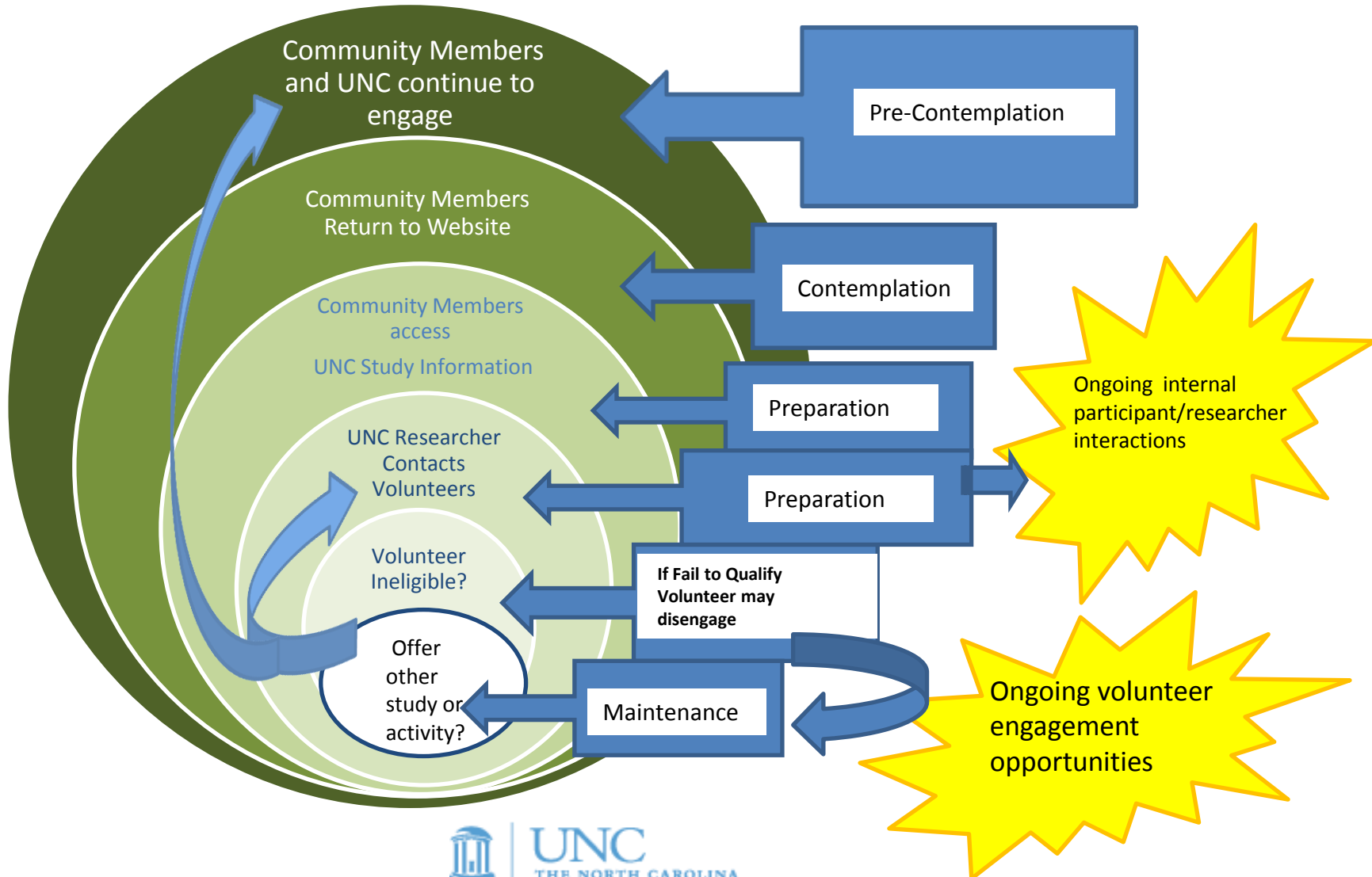
## Coordinated with Volunteer Readiness/TraCS reinforcement



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# Community Integrated Portal to Facilitate Volunteer Retention Process



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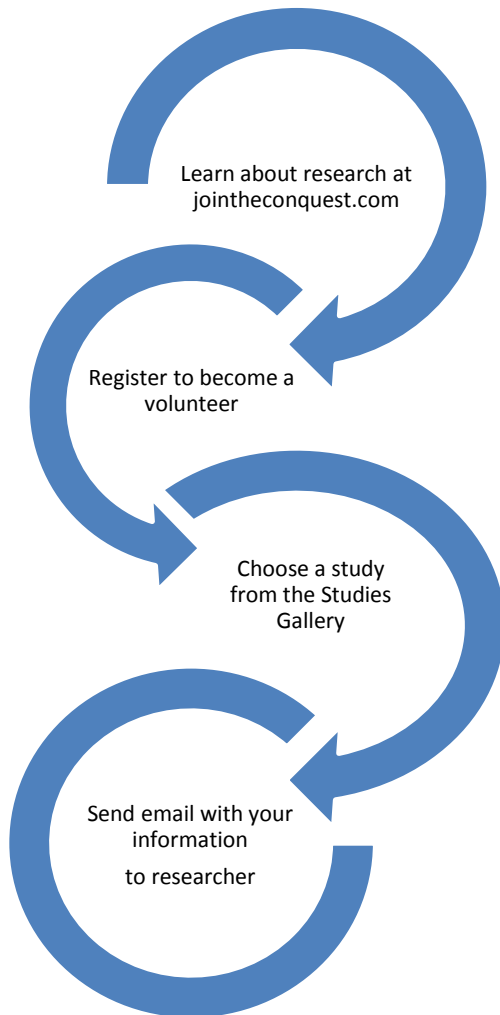
# Join the Conquest!

## (UNDER CONSTRUCTION)



# Join the Conquest! The UNC Research Volunteer and Studies Exchange System

## VOLUNTEER



## RESEARCHER



# Advertising Template

- Form will be available online in CRMS and at TraCS. Will require IRB approval like all advertising
- Designed to accommodate volunteer health literacy limitations
- Creates a “Reader’s Digest” version of protocol and study inclusion/exclusion and details
- Is a powerful free advertising tool
- Engages the larger community in research that is beneficial for improving community health

# Why Do Clinical Research?



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# Discussion

## Recruitment Strategy Topics

- Is it about you or is it about the subjects?
- Throwing advertising at slow recruitment
- General marketing without a strategy
- Adjusting clinic flow to timelines vs timelines to clinic flow
- Entering inflated recruitment projections in your IRB application
- Competing or cooperating with other sites

# Human Research Information

- UNC Research Recruitment Services
  - <http://tracs.unc.edu>
- ICH Guidelines
  - [http://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Efficacy/E6\\_R1/Step4/E6\\_R1\\_\\_Guideline.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf)
- US Office of Human Research Protection
  - <http://www.hhs.gov/ohrp/education>
- American Association of Clinical Research Professionals
  - <http://www.acrpnet.org/MainMenuCategory/Resources/ForResearchParticipants.aspx>
- NIH Research Volunteer Information
  - <http://www.nih.gov/health/clinicaltrials/index.htm>

# Current TraCS Recruitment Tools/Services

- Email or call NC TraCS for a recruitment services consult
- Determine recruitment feasibility using standard or custom data marts from CDW data
- Complete a Recruitment Plan using the social marketing approach
- For a consult - email TraCS at [nctracs@unc.edu](mailto:nctracs@unc.edu)
- The TraCS website is [www.tracs.unc.edu](http://www.tracs.unc.edu)



# NC TraCS Recruitment Services Mission

- **Optimize clinical research recruitment efforts across UNC CH and affiliates**
- **Implement a diverse, community-sensitive volunteer research recruitment model**
- **Create digital recruitment tools including a web-based volunteer registry**
- **Expand awareness of clinical research as a component of medical services quality improvement**



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# Questions?



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