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## Effective Strategies for Patient Recruitment and Retention

Beth Harper, BS, MBA  
President, Clinical Performance Partners, Inc.

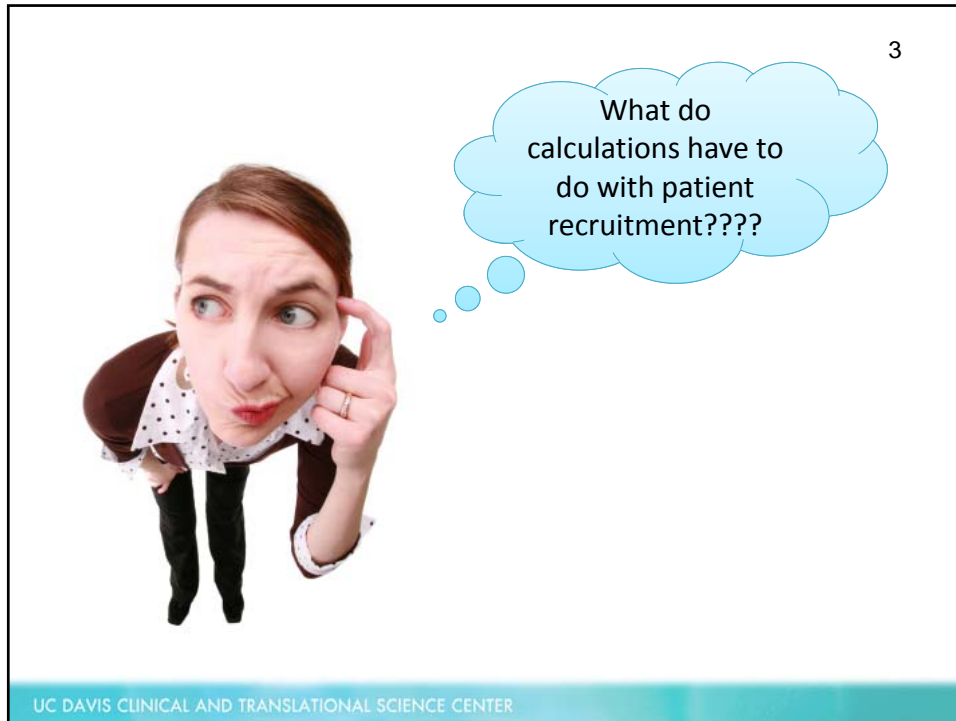
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## Do You Have Your Calculators Ready?

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## Patient Recruitment is Difficult!

- But, not as hard as calculus!
- Like any mathematical problem, it can be solved with a formula called the

# CTPQ

Clinical Trials  
Participation  
Equation

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## Patient Recruitment is Also Serious Business...

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- **But, it doesn't mean we can't have some fun learning about it!**



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## ground rules

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- **Your questions are welcomed throughout**
  - we will leave time for questions at the end as well
- **This session will be informal and interactive**
- **Your participation is encouraged**
- **We can discuss study-specific examples however, please protect confidential information!**

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## Learning Objectives

- **At the end of this session you should be able to:**
  - Explain the components of the Clinical Trials Participation Equation (or CTPQ)
  - Describe how to use the CTPQ to analyze current or anticipated enrollment challenges
  - Illustrate how the CTPQ is used to identify and prioritize study-specific tactics for enhancing patient participation in clinical trials

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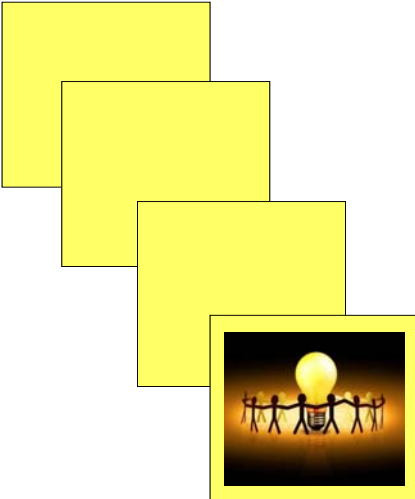
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Think about a current  
challenging trial  
(one that is behind in  
enrollment)...



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What are the main factors contributing to poor enrollment from the **Patient's Perspective?**

*(i.e., why might patients / families NOT want to participate in the trial?)*

Please list all ideas on separate sticky notes (**one** idea per note) – hold on to these for a moment

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## The CTPQ Formula

Clinical Trial Participation  $f\left(\frac{AE + CRC}{PI}\right)$

(it's not what you think!)

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## The CTPQ Theory

A Subject's\* Willingness to Participate in a Clinical Trial is a Function of:

The diagram illustrates the CTPQ Theory. It features a horizontal line with five colored boxes above it and two boxes below it. The boxes above the line are: Awareness Appreciation (purple), Education Expectations Environment (green), Credibility (blue), Relationship Responsiveness Resources (pink), and Communication (light blue). The boxes below the line are: Peril (risk) (orange) and Inconveniences Impact of "Influencers" (red).

\*subject, patient, volunteer, participant and/or their family member / care giver

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## Clinical Trials Participation is a Function of:

- The subject's **awareness** of the study opportunity and the extent to which they feel their participation is **appreciated** by the sites and research sponsor
- 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 as well as the **expectations** the subject has re: benefitting from the trial and the comfort and quality of the clinical research **environment**
- The **credibility** of the site staff conducting the trial (and interacting with the subject)
- The strength of the **relationship** the site has with the subject and how **responsive** they are to subject inquires and needs as well as the **resources** available (or impact on financial resources) to the patient/family
- 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 participation in the study as well as the strength and impact of key **influencers** (e.g., GP, family members) on the subject's decision to participate

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## To Increase Patient Participation in a Clinical Trial... 13

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

Increase the numerator

Decrease the denominator (where feasible)

*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 keep the study in a reasonable balance. When the level of Peril or Risk, Inconvenience or Impact of Influencers is high, the more difficult it will be to ensure successful study participation.*

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## Categorizing Your Results 14

□ Please post sticky notes from your brainstorming discussion on the flip chart that best corresponds to the AE + CRC / PI Categories

Awareness / Appreciation

Education / Expectations / Environment

Credibility

Relationship / Resources / Responsiveness

Communication


Peril (risk)

Inconvenience / Influencers

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What Observations  
Do You Have?



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## Discussion

- **Why did we look at this from the Patient's Perspective?**
- **What patterns emerged?**
- **Other thoughts, comments, questions?**

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## Is Your Study in Balance?

If not, which “levers” can you influence to achieve a better balance to recruit and retain subjects?

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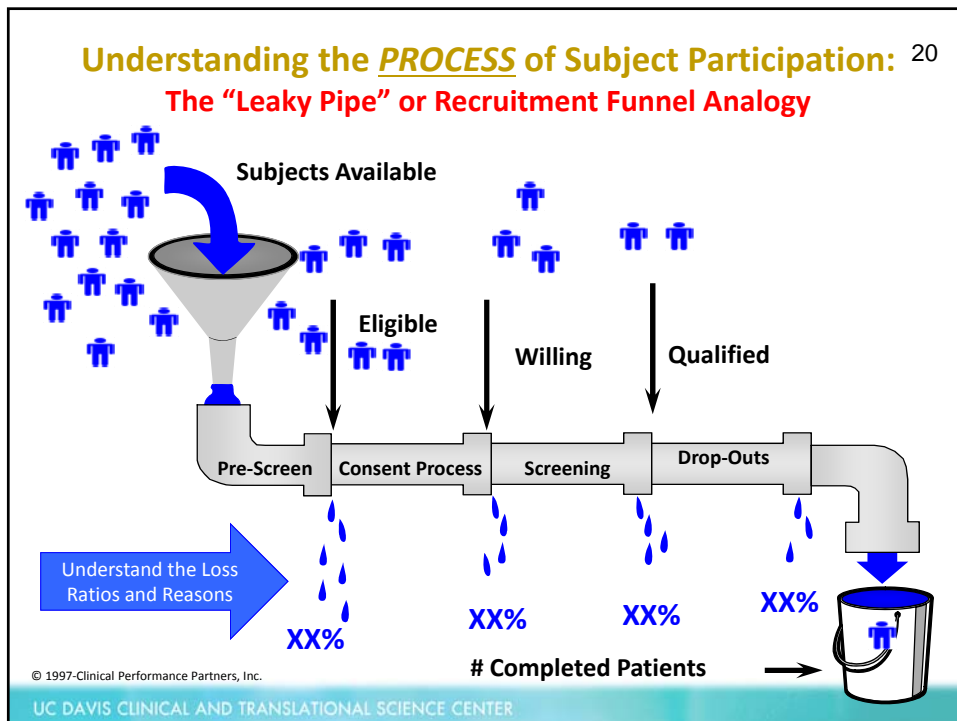
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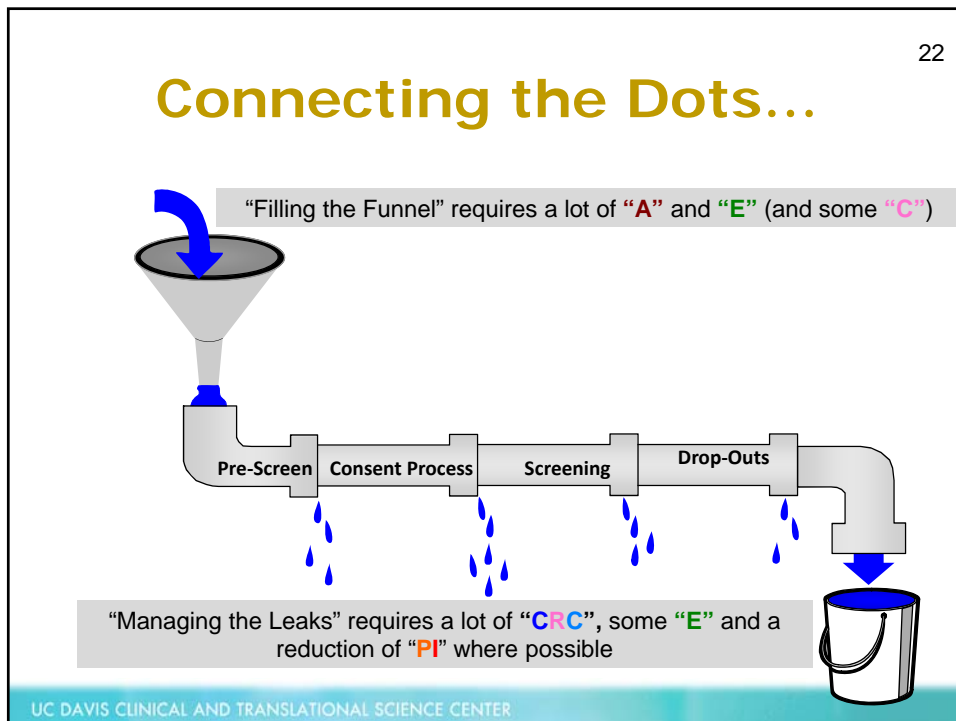
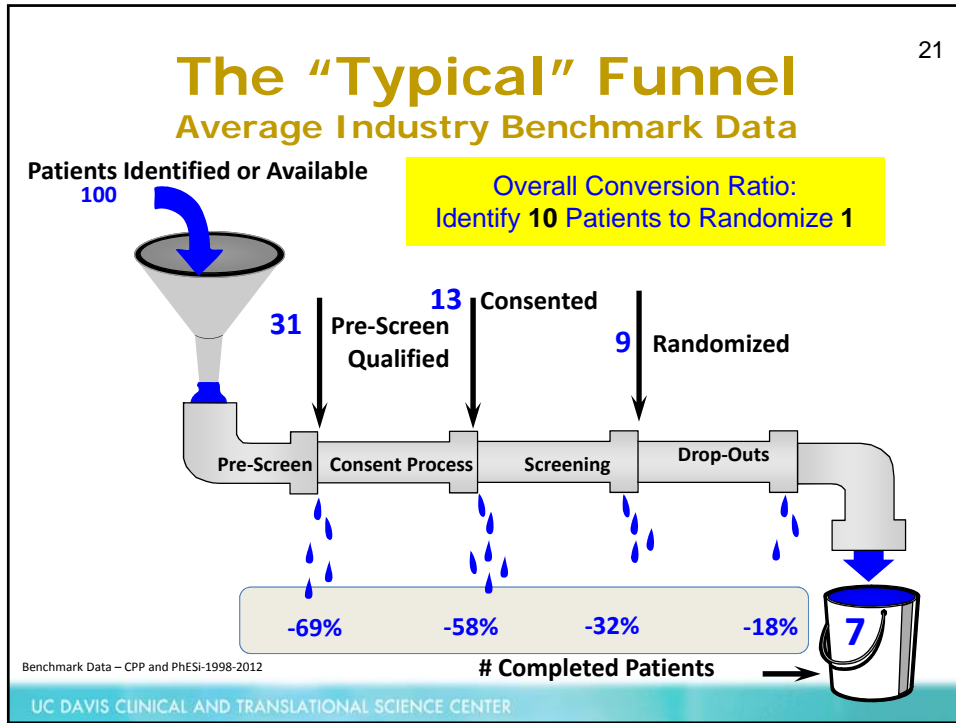
## Where Things Often Go Wrong

There is a disproportionate emphasis on study awareness building tactics at the expense of the other factors...

Awareness Building is only 1/7<sup>th</sup> (or less) of the equation, so focusing on this alone won't solve most recruitment problems.


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## Solving the Equation



Now that you know the basics...

Take a few moments to share best practices and ideas with your colleagues

- Half of the room will work on the front page and half will work on the back page

Please complete the following worksheet and be prepared to discuss your recommendations

You will have 5-10 minutes!

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| CTPQ Factor  | Solutions, Ideas, Best Practices |
|--|----------------------------------|
| Building awareness of the study – within your institution                              |                                  |
| Building awareness of the study – within the public at large                           |                                  |
| Recognizing or appreciation the subject's contribution                                 |                                  |
| Enhancing the subject's understanding about clinical research in general               |                                  |
| Enhancing the subject's understanding about clinical research about a particular trial |                                  |
| Ensuring a comfortable and patient-friendly environment                                |                                  |
| Setting and managing expectations with the subject / families                          |                                  |
| Enhancing credibility of the staff interacting with the subjects                       |                                  |

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| CTPQ Factor  | Solutions, Ideas, Best Practices |
|--|----------------------------------|
| Enhancing interim and ongoing communication with the patients by the CRC |                                  |
| Enhancing interim and ongoing communication with the patients by the PI  |                                  |
| Responding to patient / family concerns / questions                      |                                  |
| Facilitating adequate resources for the subjects to participate          |                                  |
| Reducing risk / addressing safety concerns                               |                                  |
| Minimizing study burdens and inconveniences                              |                                  |
| Keeping important influencers informed and engaged                       |                                  |

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## Discussion

- **Who had the most ideas?**
- **The most “creative” ideas?**
- **Which were easiest or most difficult to address?**
- **Other thoughts, comments, questions or observations?**

*Please leave your worksheets. I will compile all of the ideas and send a follow-up after the Forum so you have comprehensive list of ideas and recommendations!*

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## Need More Inspiration?



Clinical Research  
Recruitment & Retention Tactics

1001 Ideas to Enhance Study Awareness and  
Encourage Participation in Clinical Trials

- **There really are unlimited opportunities for building study awareness and enhancing trial participation!**

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## If You Believe the CTPQ...

- **Which aspects if any would change based on the**
  - Therapeutic area or indication?
  - Phase of trial?
  - Type of trial (drug, device, vaccine, etc.)?
  - Specific trial population (e.g., pediatric, elderly, minority populations, rare diseases)?
- **Do all factors need to be address for all trials?**

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## Tips for Proactive Planning

- **During the feasibility assessment (protocol development) stage**
  - Use the CTPQ to think through all of the possible factors that might impact successful study participation
  - Discuss with the entire team and get consensus on which factors you believe will be an issue for the trial
  - Rate and rank the factors that have the greatest likelihood of making a difference (lowest scores)
  - Determine WHAT action could be taken and estimate HOW MUCH it would cost to address these issues
  - Collectively agree on which initiatives you will incorporate into your budget and recruitment action plan

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## Tips for “Rescuing” Studies Behind in Enrollment

- **Use the CTPQ to help evaluate potential root causes from the Patient Perspective**
  - There may be other protocol, sponsor, financial issues as well so don't forget to address these
- **Determine which factors are at play and again, rank and rate the impact on enrollment if you could “fix” the problem**
- **Brainstorm on possible interventions or solutions for each of the factors that are most likely to have an impact (the lowest scoring items)**
- **Determine as a team which interventions you will pursue and put in place your action plan (approvals, budget, materials, etc.)**
- **Monitor progress and re-visit the CTPQ periodically**

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## Tips for Post-Study “Lessons Learned” Analysis

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- Conduct a post-hoc lessons learned session
- Comment on what worked, what didn't and why...what you would do differently next time
- Look at the patterns and issues across studies
- Use the formula and lessons learned as a starting point for future trials to ensure that you proactively address the most common factors next time!

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## Re-Cap

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Clinical Trial Participation  $f\left(\frac{AE + CRC}{PI}\right)$

- Can you name all of the elements of the formula?
- What's the goal?
- Which factors are most likely to have the biggest impact on successful participation?
- Which factors need to be addressed for a particular trial?


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Think of the CTPQ as your recruitment and retention “Super Hero” – call upon it frequently for help in planning and troubleshooting enrollment issues!

Any lingering questions?



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## Did We Meet Our Learning Objectives?

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## THANK YOU!

- **Happy Recruiting!**

- [bharper@clinicalperformancepartners.com](mailto:bharper@clinicalperformancepartners.com)
- 817-946-4782



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