

# The Clinical Trial Participation Equation (CTPQ)

*A Formula for Patient Recruitment and Retention Success in Clinical Trials*



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

## What is it?

A formula for evaluating and understanding the factors that influence a subject's willingness and ability to participate in a clinical trial



## Where did it come from?

Developed by a seasoned clinical research professional with over 20 years of experience, the formula captures lessons learned from troubleshooting hundreds of trials in "rescue mode"

## How is it used?

The formula helps site and study teams anticipate where they might have challenges (or are experiencing challenges) and the key levers that can be used to enhance enrollment and minimize drop-outs in clinical trials

**A Subject's Willingness to Participate is a Function of:**

Awareness  
Appreciation

Education  
Expectations  
Environment

+

Credibility

Relationship  
Responsiveness  
Resources

Communication

Peril (or Risk)

Inconveniences  
Impact of  
"Influencers"



## Specifically, Clinical Trial 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 investigative site 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 regarding 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 and their family)

The strength of the **RELATIONSHIP** the site staff has with the subject, how **RESPONSIVE** they are to subject inquiries and needs as well as the **RESOURCES** available to (or impact on financial resources of) the subject / 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 study participation, as well as

The strength and impact of key **INFLUENCERS** (e.g., personal physician, family members) on the subject's decision to participate

### To Increase Participation in a Clinical Trial



These factors must be kept in balance!

Any time you increase the "numerator" your chances of success increase. But, it is especially important to do even more "AE + CRC" when the level of "PI" increases.

When the level of Peril, Risk, Inconvenience or Impact of Influencers is high, it will be more difficult to ensure successful study participation unless the denominator can be decreased or the numerator increased.

### Where Things Often Go Wrong...

Clinical study teams and research sites often place disproportionate emphasis on the "AWARENESS" part of the equation, implementing a variety of traditional and social media tactics to build study awareness.

However, while important, a subject's awareness of the trial is only 1/7th of the equation and failure to address the other elements will often not equate to improved enrollment performance.





# Solving the Equation

## Tips for Proactive Study Planning



### *During the Protocol Development and Feasibility Assessment Stages:*

- Think through all of the possible "CTPQ" factors that might impact successful study participation
- Discuss with all study team stakeholders (within and amongst) the research sponsor, CRO and investigative site and get consensus on which factors you believe will have the greatest impact for the particular trial
- For the high impact items, determine WHAT action could be taken to address each factor and HOW MUCH it will cost to address these issues
- Collectively agree on which initiatives you will incorporate into your budget and recruitment action plan (RAP)
- Document what is and isn't working and periodically re-assess the formula and your action plan and adjust as needed

## Tips for 'Rescuing' Studies Behind in Enrollment

- Use the CTPQ formula to evaluate potential root causes from the subject's perspective about why they may not be participating
- Determine which factors are at play and rank and rate what the impact on enrollment and retention would be if you could fix or address these issues
- Brainstorm on possible interventions or solutions
- Determine which interventions you will pursue and put in place your action plan (e.g., develop materials, secure approvals, etc)
- Monitor progress and adjust as needed



Please contact me if you would like a complimentary copy of the "1001 Ideas to Enhance Clinical Trial Participation" booklet which maps a comprehensive list of solutions to the CTPQ formula!

