



PARTICIPATING IN A CLINICAL TRIAL

PATIENT ADVOCACY WORKSHOP

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**NATIONAL CENTER FOR
HEALTH RESEARCH**

The Voice For Prevention, Treatment And Policy

WHY DO WE NEED CLINICAL TRIALS?

- Does the new treatment work in humans?
- Is the new treatment safe?
- Do the benefits of the new treatment outweigh the possible risks?



A high quality clinical trial is the gold standard in medical research

COMPONENTS OF A CLINICAL TRIAL

A **treatment** trial examines safety and effectiveness of a **treatment**

- Comparison group may be:
 - Placebo
 - Another treatment
- Endpoints or outcomes may be:
 - Surrogate endpoints: tumor shrinkage, blood pressure
 - Health endpoints: overall survival, death from heart disease
 - Quality of life outcomes: fatigue, ability to care for oneself



Have you participated in a clinical trial?
How was your experience?



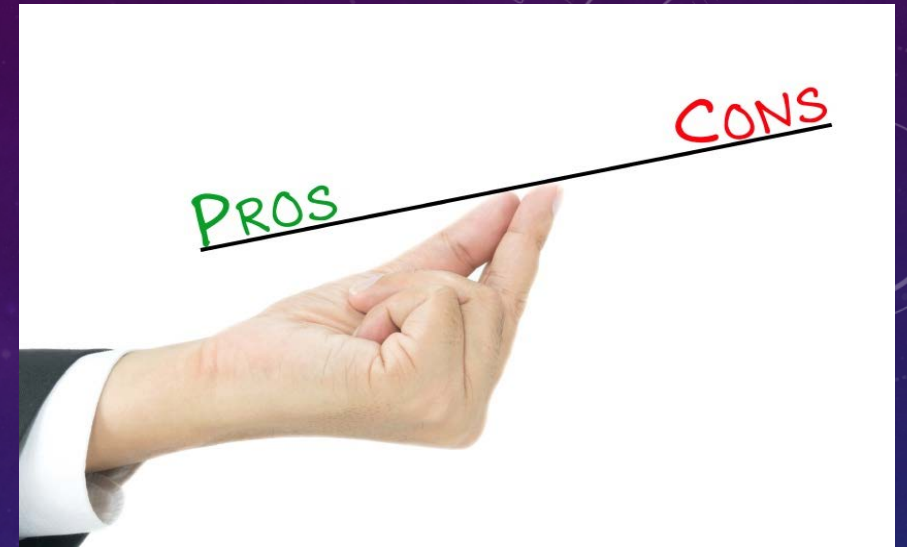
WHO PARTICIPATES IN A CLINICAL TRIAL?

- Only 35% of people say they would enroll in a clinical trial
 - Concerns include:
 - Cost
 - Side effects
 - Placebo
 - Location not convenient
- Only 4% of people actually enroll in a clinical trial
- 40% of people have a positive view of clinical trials
 - After learning more about them, 60% of people view trials favorably

WEIGHING THE PROS AND CONS

Possible Benefits

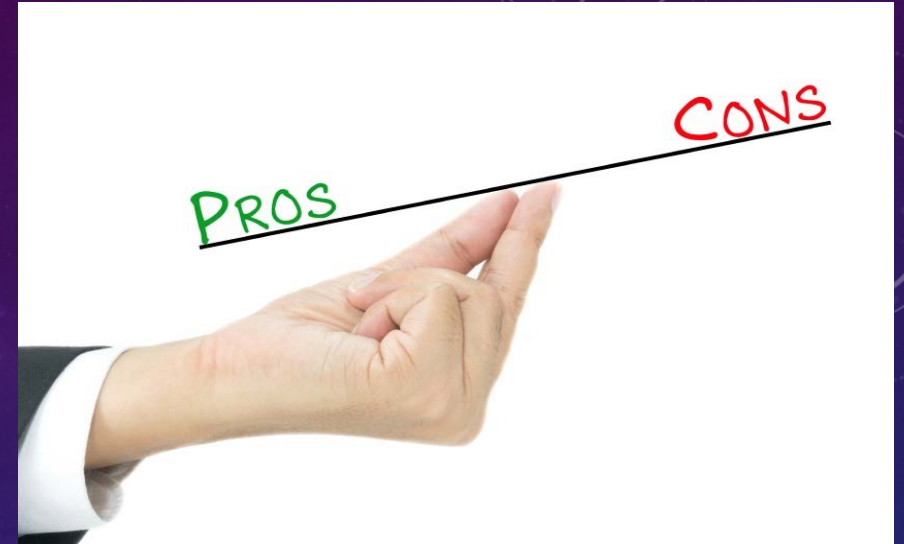
- Clinical trials usually offer high-quality care
- If a new treatment is proven to work and you are receiving it, you may be among the first to benefit
- You are taking an active role in a health decision that affects your life
- You have the chance to help others and improve treatment



WEIGHING THE PROS AND CONS

Possible Drawbacks

- New treatments are not always better
- You may be assigned to the control group – a drawback if the new treatment is effective
- New treatments may have side effects that doctors do not expect
- Even if a new treatment has benefits, it may not work for you
- Health insurance may not cover all of the costs of participating





What are your pros and cons for participation in a clinical trial?

QUESTIONS TO ASK

- Why is the trial being done?
- What are the potential risks? Benefits?
- Will there be any cost to me? What if I am harmed?
- How will participation impact my daily life?
- What are my other treatment options?
- Who is funding the study?





What do you think is important to ask?
If you have participated in a clinical trial, what
do you wish you would have asked prior to
participation?

HOW ARE CLINICAL TRIAL PARTICIPANTS PROTECTED?

- Ethical framework: Declaration of Helsinki
- Informed consent
- Institutional review boards (IRBs)
- Data safety and monitoring boards (DSMBs)



If you participated in a clinical trial, were you protected?

HOW TO DISCUSS CLINICAL TRIAL PARTICIPATION WITH YOUR DOCTOR



- Consider bringing a friend or family member to your appointment to help listen to the information
- Prepare a notebook and keep a list of your questions
- Ask if your current physician can continue to treat you or if you will need to change physicians to participate in the study
- Be sure you know your diagnosis, tests already performed, medications you are taking, and any other conditions you may have

FINDING A CLINICAL TRIAL: CLINICALTRIALS.GOV

- Site launched in 2000; results database launched in 2008
- Free public access to clinical studies
- Data submitted by sponsor or principal investigator of study
- Registration requirements vary:
 - US law
 - Academic journals
 - Institutions, funders, and IRBs



SEARCHING CLINICALTRIALS.GOV



Has anyone used clinicaltrials.gov?

How was your experience?

<https://clinicaltrials.gov/>

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. Learn more [about clinical studies](#) and [about this site](#), including relevant [history, policies, and laws](#).

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Additional Resources

- NCI-supported trials: <http://www.cancer.gov/about-cancer/treatment/clinical-trials/search>
- Disease advocacy groups
- Academic institutions
- Drug and biotechnology companies
- Clinical trial listing services
 - BreastCancerTrials.org
 - CenterWatch.com
 - eCancerTrials.com
 - EmergingMed.com
 - EvitiClinicalTrials.com
- World Health Organization International Clinical Trials Registry Platform (ICTRP)





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