



CANCER SUPPORT COMMUNITY

A Global Network of Education and Hope

Thank you!



“Terminally ill patients and their loved ones deserve nothing but the highest quality care.”
Dr. Harry Hynes

Cancer Support Community

OUR MISSION:

To ensure
that all people
impacted by
cancer are
empowered
by knowledge,
strengthened
by action, and
sustained by
community.



Cancer Support Community



Innovation in Survivorship Research

- 1,688,780
- 15.5 million
- 67 percent
- 17 percent



Patient Perceptions Have Changed

WHY ARE CLINICAL TRIALS CONDUCTED?	% ENDORSING
Find out if a new treatment (not yet approved by Food and Drug Administration) works	83.0%
Test whether a new treatment is safe	75.5%
Find better ways to treat symptoms from cancer and cancer-treatment	69.4%
Compare a new treatment to a treatment that is already FDA approved	69.2%
Track people over time	62.1%
Improve quality of life	58.3%
Find out if a new treatment will help a specific patient	56.5%
Compare two FDA approved treatments	51.2%
Find better ways to detect cancer early	47.2%
Find better ways to prevent cancer	44.1%
Provide new treatments for cancer to patients who cannot afford them otherwise	38.7%

www.cancersupportcommunity.org/clinicaltrials

Some Have Not

	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE OR DISAGREE	AGREE	STRONGLY AGREE
I would have access to new, innovative treatments	0.9%	2.0%	20.8%	50.5%	25.8%
I trust that the health care team running the clinical trial has my best interest at heart	4.3%	9.5%	28.2%	40.1%	18.0%
I am uncomfortable with being randomly assigned (like tossing a coin) to determine which treatment I receive	6.3%	17.6%	21.9%	37.9%	16.3%
Cancer clinical trials are the only way to find new treatments for patients	3.2%	23.0%	24.8%	34.3%	14.6%
I do not have concerns that I will be used as a "guinea pig" for research	12.6%	17.1%	26.6%	30.4%	13.3%
A clinical trial would have more appointments and procedures	3.4%	13.6%	25.9%	44.0%	13.2%
I have financial concerns about participating in a clinical trial (for example insurance deductibles or other out-of-pocket costs)	19.0%	22.4%	25.6%	22.0%	10.9%
I have logistical concerns about participating in a clinical trial (for example time off work, childcare)	16.1%	25.3%	21.9%	26%	10.6%
I fear the treatment wouldn't work	8.1%	13.8%	40.4%	28.0%	9.7%
I have unanswered questions about clinical trials	15.8%	21.8%	30.0%	25.9%	6.4%
I would receive a placebo/"sugar pill"	10.3%	16.4%	49.3%	18.7%	5.3%

And Some Are New

	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE OR DISAGREE	AGREE	STRONGLY AGREE
I would have access to new, innovative treatments	0.9%	2.0%	20.8%	50.5%	25.8%
I trust that the health care team running the clinical trial has my best interest at heart	4.3%	9.5%	28.2%	40.1%	18.0%
I am uncomfortable with being randomly assigned (like tossing a coin) to determine which treatment I receive	6.3%	17.6%	21.9%	37.9%	16.3%
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Words to Live By

The Belmont Report

The term "benefit" is used in the research context to refer to something of positive value related to health or welfare. Unlike, "risk," "benefit" is not a term that expresses probabilities. Risk is properly contrasted to probability of benefits, and benefits are properly contrasted with harms rather than risks of harm.

Accordingly, so called risk/benefit assessments are concerned with the probabilities and magnitudes of possible harm and anticipated benefits. Many kinds of possible harms and benefits need to be taken into account. **There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding benefits.**

While the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked.

Patient Experience in Today's World

Table 2. Item Discrimination Index for the 25 Items of CancerSupportSource™ and proportion of participants who rated they were somewhat to very seriously concerned about each item

Problem-Related Distress Item	Item discrimination index	Somewhat to very seriously concerned
		%
Changes or disruptions in work, school or home life	0.86	39.4
Feeling sad or depressed	0.85	37.5
Feeling too tired to do the things you need or want to do	0.85	41.4
Worrying about the future and what lies ahead	0.85	56.2
Feeling nervous or afraid	0.81	32.3
Ability to exercise or be physically active	0.76	37.1
Pain and/or physical discomfort	0.75	31.5
Worrying about family, children and/or friends	0.71	33.1
Body image and feelings about how you look	0.71	40.6
Sleep problems	0.70	43.4
Preparing for an upcoming treatment decision	0.67	22.3
Coping with your feelings	0.67	66.5
Coping with side effects of treatment (nausea, swelling, etc)	0.64	24.3
Health insurance or money worries	0.62	33.1
Knowing how to communicate best with your doctor	0.61	35.5
Feeling lonely or isolated	0.61	21.1
Moving around (walking, climbing stairs, lifting, etc.)	0.61	25.9
Finding reliable information about complementary or alternative practices	0.55	33.1
Recent weight change (gain or loss)	0.49	31.5
Problems in your relationship with your spouse/partner	0.47	21.1
Intimacy, sexual function and/or fertility	0.47	34.7
Transportation to treatment and appointments	0.24	6.8
Tobacco or substance use-by you or someone in your household	0.22	7.2
Eating and nutrition	0.20	90.4
Considering taking your own life	0.07	1.6

Miller, M.F. (et al.). 2013 Discriminatory power of a 25-item distress screening tool CancerSupportSource ®: A cross-sectional survey of 251 cancer survivors. ASCO. 10

Clinical Trial Endpoints

In clinical trials, an event or outcome that can be measured objectively to determine whether the intervention being studied is beneficial. The endpoints of a clinical trial are usually included in the study objectives. Some examples of endpoints are survival, improvements in quality of life, relief of symptoms, and disappearance of the tumor

NCI Dictionary of Cancer Terms, accessed April 24, 2017

11

Patient Experience in Clinical Trials

- Current Patient Reported Outcomes (PROs)
 - Disease symptoms
 - Treatment side effects
 - Physical functioning
- Future Patient Experience Outcomes (PEOs)
 - Disruption of work, family, or school life
 - Concerns about transportation
 - Body image
 - Other

Seamless Integration into Clinical Trials

Patient experience endpoints must be:

- Included in most trials
- Specific to a trial
- Documented and reported



Seamless Integration into Clinical Trials

Why?

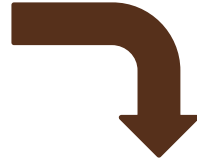
- Improved patient outcomes
- Reduced clinical trial abandonment
- Meaningful information for decision making



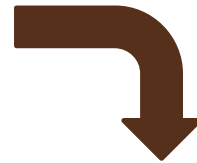
Seamless Integration into Clinical Trials

How?

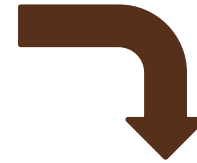
Patient enrolls in trial



Routine screening visit two



Appropriate intervention applied



Patient re-screened - timing determined by trial

**Measurement and intervention
documented and reported**

Next Steps

- Proof of concept study
- Ongoing dialogue with NCI, FDA, researchers
- Patient Experience in Research Act, 2017



Cancer Support Community

So that no one faces cancer alone[®]



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17