

Smart Phrases for Discussing Clinical Trials with Patients and Caregivers

Concern	Response Objective	Example Responses
Fear of being a “guinea pig”	Validate concern* Emphasize rigorous oversight in clinical trials	“Thanks for sharing your concern. I have heard that a lot from other patients. What does that mean to you to be a guinea pig?” “I understand. The fear of being a guinea pig and having no control is a common concern for many patients. Clinical trials are carefully designed studies that put the health and safety of patients first.” [Adapted from LLS – LINK] “That is a perfectly valid concern. I can assure you that you won't be treated like a ‘guinea pig.’ It is true that clinical trials are designed to test treatments or answer medical questions, but that doesn't mean you won't get excellent care. Many trial participants feel they get even more attention from their medical team.” [Adapted from ACS – LINK]
Side effects and risks	Highlight close monitoring during trials and support for managing side effects	“All treatments, even those that are standard of care, will have side effects. Managing side effects is an important part of clinical trials and participants are closely monitored.” “Yes, all clinical trials have risks, just like any medical test, treatment, or procedure does. However, many people with cancer find that the potential benefits - such as access to new treatments and extra medical attention - outweigh these risks.” LINK

Belief that standard treatments are better	Link clinical trials to the development of existing treatments.	"I can see why you would be concerned about that. Keep in mind that existing standard treatments were once part of clinical trials. In fact, when clinical trials show better results than the current standard, they may become the new standard treatment." [reference LINK]
Clinical trials are a "last resort" or means giving up on other treatments	Explain that trials can be an additional option rather than a replacement and that clinical trials can also be part of early treatment strategies.	"I can see why that would feel concerning thinking this is a last resort. Actually, cancer clinical trials exist for all types and stages of cancer, as well as for cancer prevention. Considering a clinical trial for your treatment does not mean that there is no hope or no other treatment options" [source LINK] "Participating in a clinical trial doesn't mean giving up on standard treatments; it can complement your current care." "You don't have to exhaust all other options before joining a clinical trial; trials can be part of your treatment plan at any stage."
Receiving a placebo	Clarify role of placebos in CCTs	"Placebos are rarely used alone in clinical trials unless there is no known effective treatment. Most cancer clinical trials do not use placebos unless they are given alongside an active drug." LINK "There are many different types of clinical trials and most of them do not include placebos. When we are reviewing clinical trial options, we can pick a trial where you wouldn't be in a situation where you are getting a placebo by itself."
Doubt about effectiveness of experimental treatments	Reinforce potential benefits of participating in early/new treatments.	"Before a treatment becomes a clinical trial, scientists have already shown that it is promising. In fact, part of the reason to participate in a trial is to get early access to cutting edge treatments."

No long-term follow-up data on treatment	Reassure patient of making a shared decision after considering best options together.	“Some clinical trials involve treatments that are new so we don’t know what the long-term or late effects of the treatment might be. Other clinical trials involve treatments with a known track record that have been used for a long time, so we do know what the long-term effects are. I will discuss with you each option and, we can consider whether a treatment with unknown future risks is worth considering in your situation. I will help you make a decision on what is best for you.”
Cost concerns	Highlight possible ways to manage costs.	“I am glad you brought that up. It's important to discuss this with the study coordinator because there are often resources available such as covering visit co-pays and transportation costs.”
Fear of the unknown	Reassure patient of transparency of procedures and voluntariness of trial participation. Emphasize that clear communication and informed consent are fundamental parts of clinical trial research.	“The research team will explain everything in detail, and you can ask questions at any time. Participating in the trial is completely voluntary and you can decide to stop participating at any time.” “There are true that are no guarantees. What is important is that you and I keep in touch as the trial progresses to make sure that your concerns are addressed as they come up.”
Time and logistics	Be realistic with patient that the clinical trial may result in time away from work and caregiving and extra out-of-pocket expenses. Provide empathy and encourage discussion with research team.	“It is true that participating in a clinical trial may require spending time away from home which can lead to out-of-pocket expenses, time away from work, and your family. It's important to discuss these details with the study coordinator to see what resources are available.”

Historical mistrust of medical research	Acknowledge past abuses and emphasize commitment to ethical standards	“Thank you for bringing this up – it’s important for us to talk about. You are right that tragically some patient groups, like Black patients, have been historically mistreated in clinical research. Today, in part because of that history, we have strict ethical standards and regulations to protect all participants in clinical trials.”
Lack of trust in medical system	Build trust by highlighting strict oversight	“Clinical trials are conducted by trusted medical professionals and are reviewed and overseen by ethics committees to ensure the safety and rights of participants are protected.”

Positive Appeals

Emphasizing the positive	Objective	Example Phrases
Altruism and helping future patients	Appeals to altruism, societal benefits.	“By participating, you contribute to research that can help future patients and improve cancer treatments for everyone.” “When you volunteer to take part in cancer clinical trials, you help doctors and researchers learn more about the disease and improve health care for cancer patients in the future.” [LINK]
Access to new treatments	Emphasizes advantage of accessing new treatments.	“Clinical trials give access to cutting-edge treatments that aren’t yet available to the public.”
Extra medical attention	Points out access to increased medical attention and care when participating in trials.	“Participants in CCTs usually get more frequent check-ups and closer monitoring by a dedicated medical team. In fact, these extra visits and monitoring are something that you and your family should consider when deciding whether to participate in a clinical trial.” “Many participants appreciate the extra health care they get during a study. Those involved in trials are closely monitored and cared for by both the research team and the medical staff.” [Adapted from LINK]

References and Resources

PBS – Fact and Myths about CTs:

- https://www.pbs.org/wgbh/takeonestep/cancer/resources-cancer_groups.html#:~:text=Myth%3A%20Clinical%20trials%20are%20a,well%20as%20for%20cancer%20prevention.

Educational resources:

- **Blood Cancer United (formerly The Leukemia & Lymphoma Society (LLS) resources:**
 - o Website: <https://lls.org/treatment/types-treatment/clinical-trials>
 - o Downloadable/orderable clinical trial booklet: <https://lls.org/booklet/understanding-clinical-trials-blood-cancers>
 - o “Are Clinical Trials Safe?”: <https://lls.org/treatment/types-treatment/clinical-trials/are-clinical-trials-safe>.
- **ACS – Clinical Trials: What you need to know:** <https://www.cancer.org/cancer/managing-cancer/making-treatment-decisions/clinical-trials/what-you-need-to-know.html>
- **NIH: Clinical Trials & You (The basics):** <https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics>
<https://www.nih.gov/health-information/nih-clinical-research-trials-you/educational-resources>
- <https://www.nia.nih.gov/health/clinical-trials-and-studies/clinical-research-benefits-risks-and-safety#:~:text=For%20example%2C%20you%20may%20be,that%20gets%20the%20experimental%20treatment.>

VIDEO: Addressing concerns around side effects in clinical trials

- https://www.youtube.com/watch?v=LvX6s4GzMn0&ab_channel=KnowAML

Burdens / Non-clinical expenses:

- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6693715/>
- <https://www.pbs.org/newshour/health/for-cancer-patients-clinical-trials-can-come-with-significant-out-of-pocket-costs>

Travel Expenses

- Highlight that some trials offer reimbursement, other institutions may connect patients with local support groups or organizations that help arrange housing/accommodations. Trials support may help with travel logistics.
- <https://www.moffitt.org/patient-family/preparing-for-your-appointment/traveling-for-cancer-treatment/>

Cost Coverage

- Influence of Cost-Related Considerations
 - o <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9713084/>
- Who Pays for Clinical Trials?
 - o <https://www.cancer.gov/research/participate/clinical-trials/paying>

Clinical Research Versus Medical Treatment:

<https://www.fda.gov/patients/clinical-trials-what-patients-need-know/clinical-research-versus-medical-treatment>

Extra Medical Attention

- <https://www.hopkinsmedicine.org/research/understanding-clinical-trials/why-take-part#:~:text=Many%20participants%20like%20the%20extra,helping%20with%20their%20overall%20care>.

Strict Ethical Guidelines [Lack of trust in medical system]

- <https://clinicalcenter.nih.gov/recruit/ethics.html>
- https://clinregs.niaid.nih.gov/country/united-states#regulatory_authority
- *The Importance of CT transparency and FDA Oversight*
 - o <https://www.fda.gov/news-events/fda-voices/importance-clinical-trial-transparency-and-fda-oversight>

Extra Attention / Medical Monitoring

- <https://www.hopkinsmedicine.org/research/understanding-clinical-trials/why-take-part#:~:text=Many%20participants%20like%20the%20extra,helping%20with%20their%20overall%20care>.

Will I Be a “guinea pig?” / Will I get a placebo?

- ACS: <https://www.cancer.org/cancer/managing-cancer/making-treatment-decisions/clinical-trials/what-you-need-to-know/who-does-clinical-trials.html#:~:text=People%20who%20take%20part%20in,Will%20I%20get%20a%20placebo?>
- LLS: Page 17 of this booklet: <https://lls.org/booklet/understanding-clinical-trials-blood-cancers>

Side effects oversights

- <https://www.nia.nih.gov/health/clinical-trials-and-studies/clinical-research-benefits-risks-and-safety#:~:text=Clinical%20trials%20that%20test%20an,can%20stop%20the%20trial%20early>.
- <https://www.ncbi.nlm.nih.gov/books/NBK208615/>

Don't have to exhaust all options:

<https://fightcolorectalcaner.org/facing-colorectal-cancer/colorectal-cancer-clinical-trials/>

<https://www.wcgclinical.com/insights/removing-barriers-reimbursement-compensation-participation-oncology-clinical-trials/>

WHO CCT MythBusters

- Are CTs a Gamble? <https://youtu.be/fU-JmLbcuzA?si=d2T5cjF4NmyU0p7G>
- Are CTs a Last Resort? <https://youtu.be/OKjGVN7LIP0?si=zrYQxN9uXnBCVFfH>
- How doe Medicare/caid affect <https://youtu.be/QnsN8DIINuY?si=z6w1Adov3V5ngmhy>