

7 Reasons to Consider Clinical Trials: based on your clinical circumstances

Meeting the **dual** requirements of **Good Science AND Good Medicine**

PREAMBLE AND DEFINITIONS:

We define **cure**, as an outcome where the disease never returns, or never returns to a level that is detectable or clinically relevant. ... We die of something else, unrelated to the treatments we received.

Noting that going for a cure is not always appropriate, and that it can take many years to determine if an indolent (slow growing) cancer is cured with any protocol and that we need to consider the risks of therapies that *may* have the **potential** to achieve this goal.

For example, an allogeneic stem cell transplant appears to be curative (potentially), but it also has significant risks, including treatment-related death, and therefore it might not compare favorably to management of a lower-risk disease treated with lower-risk therapies as needed.

The potential to cure depends on the type of the lymphoma (its natural history), and the available evidence from clinical trials (from preliminary to substantial), and our clinical circumstance (such as number of prior therapies, our general health and age).

The urgency to achieve a cure depends on the anticipated clinical course of the lymphoma (aggressive vs. indolent), but also sometimes the age and performance level of the patient.

Please note that we are not qualified to recommend therapies, standard or investigational; noting that even trained physicians require having first-hand information about the patient before making any treatment recommendations. By definition the true risks and potential benefits of investigational protocols are not fully understood. That is, that a protocol has a potential to provide **clinical benefit** – to improve survival or quality of life – is not a guarantee that the goal will be realized, else researchers would not need to do the study.

However, the potential of standard therapies to meet clinical needs can be inadequate for some types of lymphoma in some clinical circumstances. That is, risk and uncertainty are not exclusive to investigational therapies and in some circumstances (outlined below), investigational protocols can compare well to standard approaches.

Thus we need to ask informed questions and to **rely on experts** to help us with these complex treatment decisions – to help us **to also consider clinical trials**.

THREE BASIC GOALS OF THERAPY:

- To address a lower-risk lymphoma as needed with minimal toxicity (management)
- To achieve a durable remission or possible cure (curative intent)
- To relieve symptoms or to address select areas based on immediate need (palliative or best supportive care).

PATIENT-CENTERED CRITERIA-
WHEN TO CONSIDER TRIALS:

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WHEN TO CONSIDER A CLINICAL TRIAL:

1. Standard treatment is not yet curative or highly effective;

AND the study protocol has shown (from preliminary evidence*) that it might have the potential to cure, or to improve the outcome – leading to better and longer-lasting response with less risk and toxicity.

2. Standard treatment is curative, but relapse is common;

AND the study protocol has shown (from preliminary evidence*) that it may improve the cure rate.

3. Standard treatment is curative, but also has significant late toxicities;

AND the study protocol has shown (again from preliminary evidence*) that it might be as effective as standard treatment but safer.

4. Standard treatments are not safe for me (because of age/ illness);

AND the study protocol has shown (from preliminary evidence*) that it might have lower toxicity.

5. Observation is recommended for me (because I have an indolent cancer that does not yet require therapy);

AND the study protocol has low expected toxicity and has shown (from preliminary evidence*) that it might have the potential to delay the need for more toxic treatment.

6. The cancer is resistant (refractory) to standard therapy;

AND the study drugs work by a new mechanism – having shown (from preliminary evidence*) that it might have the potential to be effective when standard therapies are not.

7. There is no known best treatment for my cancer (a choice is provided);

AND I have no preference and the study protocol will help discover which approved protocol is best for which patient in future.

* The strength of **preliminary evidence** can range from strong to very weak. For example, outcome reports from large randomized clinical trials in a population with similar clinical circumstance and the same diagnosis could be considered **strong** evidence – providing high confidence that the outcomes in the study predict results for others in this circumstance; a small single-arm study generally provide only modest indications or signals of the potential of a protocol to meet clinical needs; and pre-clinical studies (based on animal models) are considered a starting point only – very **weak** evidence the drug or protocol could provide clinical benefit.

Patients Against Lymphoma

Providing evidence-based information about lymphoma and treatments, independent of health industry funding

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