

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

Meeting the **dual** requirements: **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 live a normal life and die of something else.

We note 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 ... 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, 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. (In some few cases, for indolent lymphoma, there is never a need to treat.)

Please note, we are not qualified to recommend therapies, standard or investigational. And by definition the true risks and potential benefits of investigational protocols are not fully understood. That is, that a protocol has a potential or possibility to improve survival (or our quality of life) is not a guarantee that the goal will be realized, else researchers would not need to do the study. However, the risks and benefits of standard therapies may be inadequate as well – depending on the type of lymphoma. That is, risk and uncertainty are not exclusive to investigational therapies.

We believe that the consideration of clinical trials should be routine. To achieve this goal we need to ask informed questions and to rely on experts to help us with these complex treatment decisions – who have first-hand information about our diagnosis and risk factors.

### THREE BASIC GOALS OF THERAPY:

- To manage the lymphoma - treat as needed with minimal toxicity
- 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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## ***Patient-Centered Criteria - When to consider a clinical trial***

### **WHEN:**

#### **1. Standard treatment is not yet curative (or highly effective);**

AND preliminary evidence\* suggests that the study protocol might have the potential to cure, or to improve the outcome – leading to better and longer-lasting remissions perhaps with less risk and toxicity.

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

AND preliminary evidence\* suggests that the study protocol might improve the cure rate.

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

AND preliminary evidence\* suggests that the study protocol might be as effective as standard treatment but safer.

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

AND preliminary evidence\* suggests that the study protocol 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 preliminary evidence\* suggests 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 – AND preliminary evidence\* suggests that the study protocol 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 or clinical reason to avoid one of the arms of a randomized study* that will help to prove which protocol is best for patients in the 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 the real world; 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*

[www.lymphomation.org](http://www.lymphomation.org) | [Support@lymphomation.org](mailto:Support@lymphomation.org)

Help finding Clinical Trials: [www.lymphomation.org/clinical-trials-gov.htm](http://www.lymphomation.org/clinical-trials-gov.htm)

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