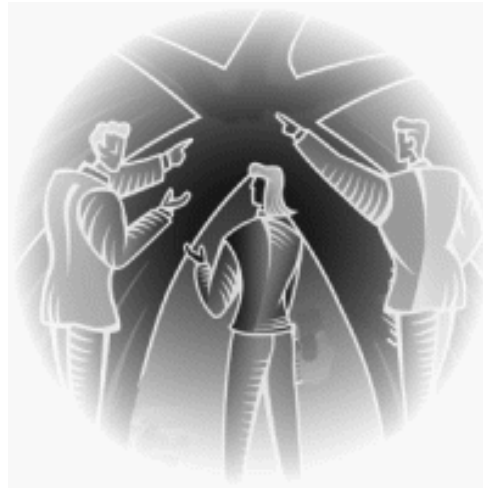


CONSIDERING CLINICAL TRIALS

based on your unique
clinical circumstances

Only trained physicians with first-hand information about your case can recommend a clinical trial.

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 be curative is not a guarantee that the goal will be realized, else researchers would not need to do the study.



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INTRODUCTION

Cure can be a feasible goal of therapy for some if not eventually all types of lymphoma, even at an advanced stage.

We define cure, as an outcome where the disease never returns, or never returns to a level that is detectable or clinically relevant.

The urgency to go for a cure depends on the anticipated clinical course.

From necessity, cure is often the goal of therapy for aggressive lymphoma. For indolent lymphomas there is less potential but also less urgency to cure. Fortunately it can remain stable for years.

Thus, we need to consider 1) the risks of the disease, 2) the risks of treatments, and 3) the potential to achieve the goal with current regimens.

The potential to cure is also based on our unique clinical circumstance, such as the sensitivity of the lymphoma to prior therapies, our general health and age.

For example, an allogeneic stem cell transplant can cure, 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.

Risk and uncertainty are not exclusive to investigational therapies and sometimes clinical trials can compare very well to standard approaches as treatment decisions – the case we make here in this pamphlet -- thus we need to ask informed questions and to rely on experts to help us with these complex decisions.

THREE GOALS OF THERAPY:

Curative intent: having the potential to achieve a durable remission or possible cure – generally with more aggressive (higher-risk) combination therapy

Management: to manage the lymphoma – treating only as needed with agents having lower expected toxicity

Palliative: to treat with the goal of relieving symptoms or to address select areas based on an immediate need (best supportive care). Palliative treatment can be disease-directed.

YOU MIGHT CONSIDER A CLINICAL TRIAL WHEN:

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 – possibly 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 from preliminary evidence* that it might be as effective as standard treatment but safer.

4. Standard treatments are not safe for me because of my age, medical conditions, or other risk factors

AND the study protocol has shown from preliminary evidence* that it has potential efficacy and lower expected 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 that it has 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 has 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.

* Preliminary Evidence

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 diagnosis could be considered strong evidence – providing high confidence that the outcomes in the study predict results for your clinical 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.

Strength of Evidence at-a-glance

Study size – larger is better

Patient selection – randomized selection is best as it provides the most objective way to compare the results of two protocols

Population – including the type of diagnosis, risk factors, eligibility, and treatment history

Efficacy Endpoints – the outcomes that were measured in the study, such as survival, progression free survival, response rate, complete response rate.

Side effects – short and long term

Follow up – how long the participants were followed (months, year, many years)