PROPOSALS (CONTINUED)

Act: Carry out biospecimen-based research to better address disease and patient heterogeneity – undiscovered biological variables that affect outcomes.

Support standardized collection and analysis of biospecimens, and data sharing, to enable:

- Efficient discovery of disease pathways, which may be targeted by new drugs.
- Discovery and validation of clinically useful biomarkers to guide the approach to treatment and selection of therapies.
- Selection of patients for stratified studies based on prognostic biomarkers and therapeutic targets.

Other Actions

Act: Help patients and caregivers to better evaluate medical claims and data and to understand standards for evidence and the drug evaluation process.

Act: Advocate for standard abstract formats to help scientists and the public quickly judge the context and meaning of studies:

> N = *300 patients with xyz, median age, treatment history, disease status …*
>
> Study type: Randomized / Single Arm / Preclinical / Review ...

Act: Help patients to review consent forms and consult independent experts.

Act: Link clinical trial-eligible patients to resources that provide travel, lodging, and financial assistance.

Examples for patients: When might I consider clinical trials?

Note: Physicians who do not participate as investigators of clinical trials are unlikely to discuss or refer patients to trials. Thus, we recommend, when feasible, that patients consult *independent* experts for the purpose of considering the *full range* of treatment options, including clinical trials.

- **Standard therapies for my type of disease are not yet curative, and I want to consider protocols that have curative potential.**
- **I'm older and/or in poor health. I need a therapy that has lower expected toxicities than standard treatments.**
- **I have indolent lymphoma and do not require therapy, but the need to treat soon is anticipated. I'd like to consider protocols that have lower expected risk, that may regress or slow progression, and that also unlikely to preclude benefiting from standard therapies later on.**
- **My disease is resistant to standard protocols. I urgently need to consider study protocols of agents with unique mechanisms of action.**
- **I need to consider studies that are aggressive (e.g., allogeneic stem cell transplantation) as I have high-risk disease or bone marrow failure.**

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The Urgent Need To Increase Participation In Clinical Trials

There is an increasing number of investigational agents for lymphomas but a limited patient pool, approximately 5% of available patients. Thus, identifying and addressing obstacles to clinical trial enrollment is vital to making progress.

Slow enrollment delays new drug and protocol evaluations, contributes to costs, and raises the financial risks of bringing new drugs to market. But most importantly, delays in enrollment costs lives.

Patient participation is key:
The objective assessments of treatment protocols are made possible by patient participation in clinical trials – the *only* path to the approval of new agents and advances in the standard of care – the gateway to more effective and less toxic therapies for patients.

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Non-profit | Evidence-based | Independent of health industry funding

PROPOSALS

Harmonize research objectives with clinical needs and treatment goals of participants

If patients fail to enroll in adequate numbers, assessment of the therapy will not be made, no matter how well the study is designed from the point of view of regulators and drug sponsors.

Act: Encourage sponsors to consult with informed patients, including scientists with the disease, when designing clinical trials.

Act: Visualize the study protocol from the patient's perspective by asking the following questions:

- Does it compare favorably to other therapy options in this setting?
- Does it unnecessarily include tests that patients fear (e.g., bone marrow biopsies)?
- Do potential side effects preclude the use of protocols that may be needed later?
- Does the protocol include accepted instruments to measure quality of life?
- In comparative studies, is there genuine uncertainty about which treatment arm is superior?
- Are predictive tests (e.g., gene profiling) used to identify who is likely to benefit?

Provide financial support for travel, lodging, and insurance coverage of routine patient care

When patients participate in clinical trials they provide a service to society and deserve our support, perhaps even compensation.

Act: Advocate for government assistance, especially for the uninsured, so that the financial limitations of individual patients do not impede progress or access to appropriate investigational therapies.

Facilitate "trial talk" between patients and physicians

Act: Help patients and physicians to easily locate appropriate clinical trials.

- Enhance the search features of ClinicalTrials.gov to help patients – the primary users of this registry – locate studies based on eligibility, clinical setting, and treatment objectives.

  See our proposal:
  www.lymphomation.org/settingsrch.pdf

- Include user-friendly descriptions of protocols that describe the study rationale as a treatment decision for specific clinical circumstances.

Act: Identify and address obstacles to the routine consideration of clinical trials in regular practice.

See our ready-to-use survey:
www.lymphomation.org/docsurvey.pdf

Act: Provide oncologists with incentives (e.g., recognition) to refer patients to trials.

Act: Involve more physicians in the administration of clinical trial protocols.

Act: Inform patients about the true risks of their disease, the potential of investigational treatments, and the limitations of standard therapies.

Act: Encourage patients to consult independent lymphoma experts to get objective opinions on investigational therapies.

Act: Advise patients to have the experts they consult contact their treating physicians in order to reach a consensus regarding treatment.

ALERT: *"... equally sad is the fact that half of the unpublished trials have failed to accrue"*

~ Gregory A. Curt, M.D., Sept 2008, The Oncologist, ***One in Five Cancer Clinical Trials Is Published: A Terrible Symptom—What's the Diagnosis?***

Regarding study designs

Act: Do comparative studies of commonly prescribed protocols when a standard is not yet determined.

Act: Develop and evaluate front-line protocols that provide a greater potential for curing disease or extending survival.

Act: Evaluate protocols for indolent lymphomas that combine or sequence low-toxicity targeted biotherapies and immune-based therapies with the goal of managing the disease with minimum treatment-related side-effects.

Act: Evaluate novel immunotherapies that may overcome how tumors escape or suppress immunity.

Act: Develop and evaluate protocols of agents with unique mechanisms of action, which may be effective against refractory lymphomas.