OVERCOMING OBSTACLES (CONTINUED)

Act: Carry out the blueprint for the **National Biospecimen Network** in order to conduct more efficient and humane drug development and evaluations:

- Standardize collection of biospecimens;
- Find novel targets using microarrays;
- Refine diagnosis and identify high- and low-risk disease;
- Find clinically useful biomarkers by identifying correlations between gene expression profiles and responders;
- Select the appropriate patients for targeted-phase studies.

The result is that smaller studies will be needed to achieve statistically significant results, providing relief from the competition for patients.

Fewer patients will be subjected to the toxicity of drugs that cannot help them.

The new favorable circumstances – replacing trial and error – will cause increased interest in trials and cancer research among patients, investigators, and commercial entities...

Other Actions

Act: Inform patients on how to better evaluate medical claims and data.

Act: Advocate for standardization of abstracts that report treatment outcomes.

Act: Help patients to review consent forms, contact investigators, and complete applications.

Act: Link patients to resources that provide travel, lodging, and financial assistance.

ABOUT US

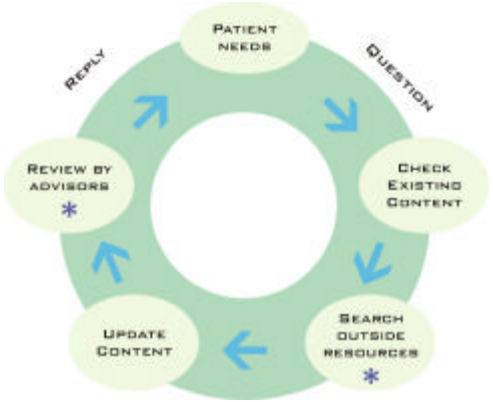
Patients Against Lymphoma

Providing evidence-based resources for patients and professionals

~ Education ~ Support ~ Advocacy ~

Guided by our scientific advisors, the peer-reviewed literature, medical professionals directly fighting lymphoma, and **patient questions . . .**

we continuously improve our website in response to visitor questions and **patient needs**



Visit us at:

Lymphomation.org

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Doctors | Guidelines at diagnosis | How to Help | Research
Side Effects | Support | Symptoms | Tests | Treatments | WebCasts

~ Independent of drug industry funding ~

INCREASING PARTICIPATION IN CLINICAL TRIALS

Patient Perspectives

To make better progress against the disease, more patients must enroll in clinical trials.

How else?

It's estimated that only 2-5% of cancer patients participate in clinical trials.

Slow enrollment delays drug evaluations, contributes to costs, and raises the financial risks of developing new drugs –

but most importantly, delays cost lives.

Patients Against Lymphoma

Helping to make progress against the disease

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Patients Against Lymphoma is a Not for Profit 501 (c) (3) organization

OVERCOMING OBSTACLES

Harmonize research objectives with patients survival goals

If patients fail to sign on in adequate numbers, the 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 informed patients, such as scientists with the disease, when designing clinical trials.

Act: Visualize the study protocol from the patient's point of view – with an appreciation that each patient has one life to experiment with.

- Does the protocol compare favorably to other options in this setting?
- Does it unnecessarily include tests that patients fear, such as bone marrow biopsies?
- Do the side effects preclude the use of treatments that may be needed later?
- Does the protocol include quality of life endpoints?
- Is there genuine uncertainty about which treatment arm is best?
- Can you disclose outcome data as it develops, to foster trust?
- Are predictive tests used to identify who is likely to benefit, such as gene profiling? *

"Given the number of articles that describe the correlative and predictive usefulness of array-based molecular classifications, especially in leukemias, these outcomes no longer elicit surprise. But perhaps they should — not only because of their clinical usefulness, as outlined in the editorial by Grimwade and Haferlach (pages 1676–1678), but also because of the rapid pace at which expression genomics is changing the conduct of clinical research.."

NEJM ~ Vol. 350:1595-1597, April 15, 2004 No 16

Provide financial support for travel, lodging, and associated tests

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.

Encourage "trial talk" between the patients and treating physician(s)

Act: Help patients and physicians to locate appropriate clinical trials by:

- Informing about the lymphoma-specific queries of ClinicalTrials.gov on our website;
- Encouraging sponsors to list all studies in ClinicalTrials.gov;
- Advocating for user-friendly descriptions of clinical trial protocols.

Act: Provide community physicians with incentives for referring patients to trials.

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

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

Act: Encourage patients to consult 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 about what treatment protocol is best for them.

NOTE: *We consult with patients and experts to identify notable clinical trials for lymphoma, and invite drug sponsors to inquire about adding protocols to our list.*

Create innovative trial designs with the potential to make a positive difference in patients' lives

The time to get creative is early in the course of the disease, when the patient has better immune competence, less tumor burden, and has had fewer exposures to toxic therapies.

Act: Develop front-line protocols, combining aggressive approaches in combination and/or in sequences with biological and immune-based therapies, that provide the potential for curing or extending survival in difficult to treat lymphomas.

Act: Develop front-line protocols for indolent lymphomas that combine or sequence low toxic target biotherapies and immune-based therapies with the goal of managing the disease with minimal toxicity.

NOTE: Without publicity, a frontline idiotype vaccine study completed accrual in two weeks.

Act: Develop protocols that induce active immunity against tumor antigens, and that may overcome ways that tumors escape or suppress immunity.

Act: Reduce reliance on quick response agents when the responses are not durable and the side effects, such as myelosuppression, contribute to complications and limit future options.

Act: Develop protocols for refractory end-stage disease that can extend survival while improving quality of life.