

# Patients Against Lymphoma



Non-Profit | Independent | Evidence-based

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*Founded in 2002*

October 21, 2011

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President:

Karl Schwartz, Participant:  
ALLIANCE Cooperative Group,  
Lymphoma Committee  
FDA Advisory Committee,  
NCI Progress Review Group  
NCI Biospecimen Best  
Practice Workshops  
Patient Advocate Faculty  
ASCO/AACR Workshop:  
Methods in Clinical Cancer  
Research

*Providing Patient Support and Evidence-Based Information on Lymphoma; and  
Advancing the Routine and Informed Consideration of Clinical Trials*

Dear

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Founding Members

Page Irby, RN  
Allan Marson, Esq.

We are Patients Against Lymphoma (PAL), a non-profit organization founded in 2002 by caregivers and survivors of lymphoma, a blood cancer that afflicts about 700,000 American citizens and many more individuals worldwide.

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Board of Directors

Jama Beasley  
Linda Gerstley, PhD.  
Carol Lee  
Dennis McComb

We are seeking financial assistance – \$25,000 in part to offset the decline in donations we typically receive yearly from many small individual donations – in order to support our work, which is already under way and by many measures provides valued service to thousands of afflicted individuals as outlined within.

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Scientific Advisors

Andrew Croaker, MD  
Maurizio Bendandi, MD, PhD  
Lucien Joubert MD  
Susan B. Spector, MS, RD, CDN  
Lynda Olender, R.N.  
A.N.P., C.N.A.A.  
Susan Olender, M.D.  
Dimitris Placantonakis, MD,  
Ph.D.  
John Densmore, MD, Ph.D.  
Allen Cohen, MD, Ph.D.  
Lurdes Queimado, MD, Ph.D.

Helping patients to become better informed about the disease and its treatments, including clinical trials, is a process:

Our initial role is to help to meet the **support** needs of patients in recognition of the considerable psychosocial impacts of the disease and treatments: The emotional stress of a diagnosis, the overwhelming sense of isolation and loss of control over one's life.

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Public Policy Advisors

Tobby Holinder, Esq.

Then, guided by our scientific advisors, we provide **evidence-based information** on lymphoma and its treatments for the purpose of helping patients to become better informed partners in their care. Importantly, the content we provide on lymphomation.org, and the resources we link to, is determined by patient questions, which likely explains the very high usage of our website.

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Patient Navigators  
/Advisors

Susan Krivacic  
Mike Lubrecht

*Lymphomation.org, website server statistics:  
50,000 to 128,000 unique visitors per month, 2010-2011*

Because our focus is on providing information, including information about clinical trials, we have chosen to be independent of health-industry funding in order to avoid even the appearance that our content is influenced by a financial conflict of interest.

Our objective is to help patients to review medical information critically and to achieve a high level of informed consent when consulting with their doctors, who often have limited time to provide complex background information about the disease and how it's treated.

For example, we teach that informed choice is an ongoing process, which requires an objective understanding of the clinical context:

- 1) the natural history – or anticipated clinical course for their type of lymphoma,
- 2) the potential benefits and risks of the current standards of care,
- 3) and an appreciation of the unique and sometimes changing risk factors – such as one's age and performance, or responsiveness to prior therapies.

The clinical context can influence how much risk is appropriate to take when treating the lymphoma and also how appropriate it might be to ask about and consider clinical trials.

A third aspect of our mission we call **research advocacy**, where we act as liaisons between the patient and research communities – helping patients to critically evaluate clinical reports, and helping clinical scientists to better understand and think like patients – in particular how clinical trial design can influence the feasibility of achieving full enrollment. We engage investigators, drug sponsors, and the major research organizations by letter and with presentations, and also by direct participation at professional conferences.

In our detailed proposal we describe our advocacy role in clinical research and evidence of our high standing in both communities<sup>1</sup>; in it we also describe ongoing projects that foster the routine and informed consideration of clinical trials.

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<sup>1</sup> Schwartz, advisors, JCO / ASCO 2009, Interest, attitudes, and participation in clinical trials among lymphoma patients with online access

Many of our projects are aimed at addressing a crisis in clinical research – particularly for lymphoma: the very low percentage of available patients who participate in clinical trials, which require completion in order to make additional progress.<sup>2</sup>

EXAMPLE FROM THE CLINICAL TRIALS PAGE:

Our tools can be used by physicians, patients, or caregivers to find studies based on the patient's clinical circumstance.

On the page illustrated here, we provide pre-built queries of the ClinicalTrials.gov registry to provide single-click access to lymphoma studies based on the type of lymphoma and treatment status.

The use of our tools does not require the visitor to provide any identifying information.

We keep track of the use of our queries by converting the commands to bitly links, which allows us to count the number of "clicks."

**Lymphomation.org**  
 About Lymphoma | Advocacy | Art | CAM & Life Style | Clinical trials | Docs & Centers | Guidelines at Diagnosis | How to Help | Side Effects | Support | Symptoms | Tests | Treatments | Types of Lymphoma

**Patients Against Lymphoma**

Clinical Trials > Find Lymphoma and CLL Trials  
 By Type of Lymphoma and Treatment Status

See How to Use below  
 Last update: 10/12/2011

Type of Lymphoma / CLL:	Find for Previously Untreated status	Find for Relapsed status	Relapsed status but NOT Transplant Lookup
<b>AIDS/HIV-related</b>	<a href="http://bit.ly/fas66l">http://bit.ly/fas66l</a>	<a href="http://bit.ly/fvW7Y2">http://bit.ly/fvW7Y2</a>	<a href="http://1.usa.gov/n30Sur">http://1.usa.gov/n30Sur</a>
<b>Anaplastic Large Cell</b>	<a href="http://bit.ly/dLVulf">http://bit.ly/dLVulf</a>	<a href="http://bit.ly/idu3uV">http://bit.ly/idu3uV</a>	<a href="http://1.usa.gov/p10TPN">http://1.usa.gov/p10TPN</a>
<b>Burkitt's</b>	<a href="http://bit.ly/hDrTtJ">http://bit.ly/hDrTtJ</a>	<a href="http://bit.ly/fiayty">http://bit.ly/fiayty</a>	<a href="http://1.usa.gov/mXrftL">http://1.usa.gov/mXrftL</a>
<b>Central Nervous System-related</b>	<a href="http://bit.ly/qZHyIZ">http://bit.ly/qZHyIZ</a>	<a href="http://bit.ly/fvpLBm">http://bit.ly/fvpLBm</a>	<a href="http://1.usa.gov/oojulj">http://1.usa.gov/oojulj</a>
<b>Childhood</b>	<a href="http://bit.ly/dNWDqn">http://bit.ly/dNWDqn</a>	<a href="http://bit.ly/eyoYn9">http://bit.ly/eyoYn9</a>	<a href="http://1.usa.gov/nWdZ3C">http://1.usa.gov/nWdZ3C</a>
<b>Chronic Lymphocytic Leukemia (CLL/SLL)</b>	<a href="http://bit.ly/hqtnd7">http://bit.ly/hqtnd7</a>	<a href="http://bit.ly/e10yeN">http://bit.ly/e10yeN</a>	<a href="http://1.usa.gov/nWicbm">http://1.usa.gov/nWicbm</a>
<b>Cutaneous (skin) presentation, (b or t cell)</b>	<a href="http://bit.ly/eMZPAj">http://bit.ly/eMZPAj</a>	<a href="http://bit.ly/fUSjZ5">http://bit.ly/fUSjZ5</a>	<a href="http://1.usa.gov/nSyNag">http://1.usa.gov/nSyNag</a>
<b>Diffuse Large B-Cell</b>	<a href="http://bit.ly/hnwBCN">http://bit.ly/hnwBCN</a>	<a href="http://bit.ly/q6jPq9">http://bit.ly/q6jPq9</a>	<a href="http://1.usa.gov/odl2NK">http://1.usa.gov/odl2NK</a>
<b>Epstein Barr Virus-related</b>	<a href="http://bit.ly/dIIAMC">http://bit.ly/dIIAMC</a>	<a href="http://bit.ly/qJqaB9">http://bit.ly/qJqaB9</a>	<a href="http://1.usa.gov/oj4abl">http://1.usa.gov/oj4abl</a>
<b>Follicular b-cell</b>	<a href="http://bit.ly/g4jlwc">http://bit.ly/g4jlwc</a>	<a href="http://bit.ly/qQjJ4Y">http://bit.ly/qQjJ4Y</a>	<a href="http://1.usa.gov/ngEk6M">http://1.usa.gov/ngEk6M</a>
<b>Hodgkins</b>	<a href="http://bit.ly/fUViZE">http://bit.ly/fUViZE</a>	<a href="http://bit.ly/h8CPOn">http://bit.ly/h8CPOn</a>	<a href="http://1.usa.gov/nwEqZu">http://1.usa.gov/nwEqZu</a>
<b>Lymphoblastic (b or t cell)</b>	<a href="http://1.usa.gov/o3yucd">http://1.usa.gov/o3yucd</a>	<a href="http://1.usa.gov/ocX3qo">http://1.usa.gov/ocX3qo</a>	<a href="http://1.usa.gov/q58JTk">http://1.usa.gov/q58JTk</a>
<b>Mantle Cell</b>	<a href="http://bit.ly/hOL82j">http://bit.ly/hOL82j</a>	<a href="http://bit.ly/ff4a55">http://bit.ly/ff4a55</a>	<a href="http://1.usa.gov/otfFdn">http://1.usa.gov/otfFdn</a>
<b>Marginal Zone / MALT</b>	<a href="http://bit.ly/gHGnaS">http://bit.ly/gHGnaS</a>	<a href="http://bit.ly/fkOD8v">http://bit.ly/fkOD8v</a>	<a href="http://1.usa.gov/qj844G">http://1.usa.gov/qj844G</a>
<b>Ocular (eye) presentation (b or t cell)</b>	<a href="http://bit.ly/gbwOX1">http://bit.ly/gbwOX1</a>	<a href="http://bit.ly/fwNkzh">http://bit.ly/fwNkzh</a>	<a href="http://1.usa.gov/r7CR7A">http://1.usa.gov/r7CR7A</a>
<b>Primary Mediastinal B-cell</b>	<a href="http://bit.ly/i4SQBN">http://bit.ly/i4SQBN</a>	<a href="http://bit.ly/i3CGVp">http://bit.ly/i3CGVp</a>	<a href="http://1.usa.gov/pzhp10">http://1.usa.gov/pzhp10</a>
<b>T-cell (all types)</b>	<a href="http://bit.ly/fb6Ldv">http://bit.ly/fb6Ldv</a>	<a href="http://bit.ly/f2jtY0">http://bit.ly/f2jtY0</a>	<a href="http://1.usa.gov/pWcF6N">http://1.usa.gov/pWcF6N</a>
Angioimmunoblastic type	<a href="http://1.usa.gov/jnnAon">http://1.usa.gov/jnnAon</a>	<a href="http://1.usa.gov/kq75bB">http://1.usa.gov/kq75bB</a>	<a href="http://1.usa.gov/qIHtd9">http://1.usa.gov/qIHtd9</a>
Mycosis Fungoides OR Sézary syndrome type	<a href="http://bit.ly/h4wcbe">http://bit.ly/h4wcbe</a>	<a href="http://bit.ly/h2X6QJ">http://bit.ly/h2X6QJ</a>	<a href="http://1.usa.gov/qEAZpF">http://1.usa.gov/qEAZpF</a>
T-cell, Peripheral (PTCL) type	<a href="http://bit.ly/f0LALB">http://bit.ly/f0LALB</a>	<a href="http://bit.ly/dRSOak">http://bit.ly/dRSOak</a>	<a href="http://1.usa.gov/ph13r8">http://1.usa.gov/ph13r8</a>
<b>Transformed (from indolent) lymphoma</b>	<a href="http://bit.ly/fs0RKO">http://bit.ly/fs0RKO</a>	<a href="http://bit.ly/ePyWcO">http://bit.ly/ePyWcO</a>	<a href="http://1.usa.gov/obMbbp">http://1.usa.gov/obMbbp</a>
<b>Waldenstrom's Macroglobulinemia</b>	<a href="http://bit.ly/eDI49o">http://bit.ly/eDI49o</a>	<a href="http://bit.ly/fnFDV6">http://bit.ly/fnFDV6</a>	<a href="http://1.usa.gov/r9IIFS">http://1.usa.gov/r9IIFS</a>

**How to Use:**

- Locate your type of lymphoma, then click the query that best matches your treatment status. The queries above are commands that locates studies in the ClinicalTrials.gov database. A list of protocols will appear in a new ClinicalTrials.gov window.
- TIP: Click the **Results on Map** tab to find studies near you.

<sup>2</sup> NEJM, 2010, Young, M.D., Cancer Clinical Trials – A Chronic but Curable Crisis

We provide our information and tools as:

- 1) Website pages (one example above)
- 2) Notices to support group members with links to our web pages
- 3) Printed brochures and checklists, letters and published reports

We do not recommend that patients participate in any specific clinical trial; nor do we promote the use of any specific therapies. We remind that we are not doctors and that even trained physicians would require first-hand clinical information before advising any person about a treatment for a life-threatening medical condition, including clinical trials. We encourage instead that patients routinely inquire if any clinical trials may be appropriate, and that the patient and family members carefully review consent documents, consult and rely on their doctor's judgment, and when feasible that patients consult independent experts prior to making treatment decisions.

We have good evidence that our impact is much larger than the size of our organization. We direct stakeholders to our well-known lymphomation website by email, by letter, or by posting notifications to our many support forums, which includes thousands of subscribers – this to ensure that the appropriate audience is aware of the information and tools we provide and how to make use of it.

We thank you in advance for reviewing our application and request for urgently needed financial assistance. We would be happy to answer any follow-up questions that you may have and to provide details of our services to patients and how we measure the effects of our work.

Sincerely,

Karl Schwartz  
President, Patients Against Lymphoma

Attached:

Executive Summary - Grant Proposal: Fostering the Routine and Informed Consideration of Clinical Trials

Letter of Support – By Doctor Maurice Bendandi, MD, PhD

# Grant Proposal

by Patients Against Lymphoma

## Advancing the Routine and Informed Consideration of Clinical Trials

### EXECUTIVE SUMMARY

Today, the ever increasing promise for medical innovation is not being matched by our ability to carry out clinical phase testing, leading to substantial delays and lost opportunities to reduce pain, suffering, and mortality from lymphomas.

#### PREAMBLE:

Patients and caregivers suffer from both their diseases and the inadequacies of existing therapies. We are the ones recruited for testing of the investigational therapies, which, in some cases, will ultimately be utilized by many of us. It is we who lose the most when clinical trials do not meet enrollment goals and fail to answer the study question ... a very common and tragic occurrence.

Since we must choose between therapeutic options, we can offer insights regarding study design, endpoints, and enrollment criteria that will not necessarily be recognized by medical professionals.

There are many clinical circumstances where a clinical trial can be at least as appropriate as standard care, and patients deserve to consider and have full access to such options. Achieving this goal can be vital to individual survival and is clearly required to make additional progress against life-threatening diseases.

As a patient group with evidence-based standards, we are well-positioned to educate other patients and communicate with clinical investigators about opportunities to participate in clinical research (which are routinely missed) - opportunities to conduct good science while practicing good medicine.

*... Clinical trial offers to the individual cancer patient treatment that should be at least equal to the best available non-experimental therapy. This equates with Good Medicine.<sup>3</sup>*

*“Improved treatments for cancer will be delayed and patient lives will be lost unnecessarily unless the efficiency and effectiveness of the clinical trials system improves.”<sup>4</sup>*

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<sup>3</sup> Kaufman D: Cancer therapy and the randomized clinical trial: good medicine?  
CA 1994 , 44:109-114

<sup>4</sup> Institute of Medicine, A National Cancer Clinical Trials System for the 21st Century:  
Reinvigorating the NCI Cooperative Group Program, April 2010 <http://bit.ly/cOu3Xc>

**Part I: EMPOWERING PATIENTS and TREATING PHYSICIANS:**

*Day or night, and without leaving home, patients can find answers to many questions in total privacy and without concern about asking a “dumb” question.*

**Helping to Meet the Support Needs of Patients**

*Recognizing the psychosocial impacts of the disease and treatments:  
The emotional stress of a diagnosis,  
the overwhelming sense of isolation  
and loss of control over one’s life*

We provide tips, links to resources, and guidance on these and related topics:

- Caregiver and patient anxiety and stress
- Communicating with doctors
- Encouragement - why there is reason to be optimistic
- Fatigue
- Financial
- Guidelines at diagnosis
- Immunizations
- Insurance
- Health Care Proxy
- Minimizing the risk of medical errors
- Pain management
- Palliative care and Hospice resources
- Patient’s stories
- Sexual / Reproductive issues
- Support groups
- Talking with your child about your cancer
- Tips for blood draws
- Treatment support - minimizing risks, reporting side effects ...

**Patient Education:**

Here are a few of the related education topics we provide on Lymphomation.org and in our support forums:

- What is lymphoma?
- How and when is it treated?

## Executive Summary (continued)

What is the standard of care?

Is the standard of care effective or curative for my subtype?

What is the level of evidence in support of the recommended treatment?

How can I optimize my clinical consults?

Who should I consult about treatments and when?

*(See Overview: Navigation and Decision Making, below)*

### **Advancing the routine and informed consideration of clinical trials**

Providing evidence-based guidance and discussion, and links to credible resources on the following topics:

- The natural history of the different lymphomas and the risks and benefits of available treatments – the basis for the consideration of any clinical trial.
- How to optimize medical consults and make the conversation about trials more routine.
- Clinical trial search tools for physicians and patients
- Notices of clinical trials of interest, with a discussion about available clinical evidence if any – to patients and treating physicians.
- 7 circumstances to consider clinical trials
- Reminding physicians of the urgency to improve the safety and effectiveness of lymphoma therapies, and the need to consider also clinical research protocols.

### **Part II: RESEARCH ADVOCACY**

- Engaging the research community about clinical trial concepts and designs, which when lacking the patient perspective can impair enrollment if not perceived as having the potential to be as good as or better than the standard of care.
  - Presentations
  - Letters and participation research conferences and programs, such as the FDA patient consulting program and advisory committee deliberations, and participation in the “The Cancer and Leukemia Group B,” an NIH-funded cooperative research group – now called the ALLIANCE.
- Providing guidance for researchers on clinical trial design: particularly that studies must have a strong clinical rationale for participation – that is, the protocol must compete well as a treatment decision against available protocols AND be able to answer clinical questions. (Good Medicine AND Good Science)
  - For example: Harmonizing Research Goals with Meeting Clinical Needs: Patient perspectives on clinical trial design  
<http://www.lymphomation.org/harmonizing-adaptive.pdf>
- Capturing and reporting on patient perspectives about clinical trials – what we fear and what are the features of desirable studies.

## Executive Summary (continued)

- Reminding of the urgent need to improve the clinical research system – to make it as efficient as it can be - that "*the patient is waiting.*"
- Citing the need: It's apparent that prescribing practices must evolve with the science. Today, we have an apparent disconnect between clinical practice and emerging science, each operating as if in two different centuries.

*FDA: "There is growing concern that many of the new basic science discoveries made in recent years may not quickly yield more effective, more affordable and safe medical products for patients."*<sup>5</sup>

*Curt, et al: "But other factors aside from a negative result may defeat a trial and its publication. Among these most prominently is the failure to accrue patients. So, while about one in five cancer trials is eventually published, equally sad is the fact that half of the unpublished trials have failed to accrue and reach endpoints; this finding represents an indictment of the review process that allows poorly designed or low-priority trials to be initiated, or delays them past their point of relevance."*<sup>6</sup>

### **Our research advocacy and patient-directed support and education services are complementary and interdependent.**

We can help investigators to think like and understand the needs of patients, including what trials are feasible to carry out, because we participate with the community on a daily basis.

We can help patients to understand and consider trials because we have a good basic understanding of the methods and purposes clinical research – because we engage in research advocacy at a very high level.

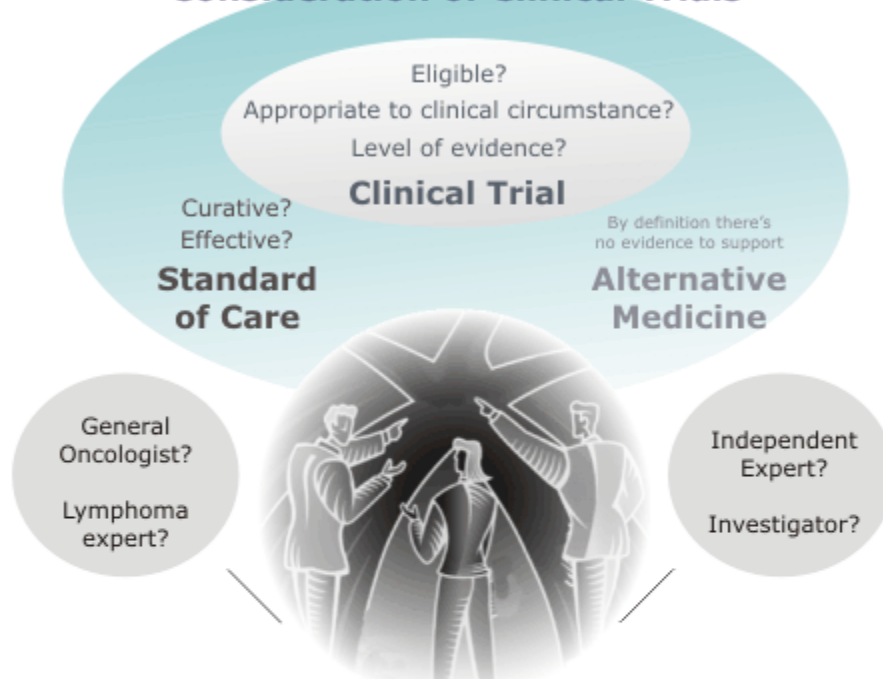
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<sup>5</sup> FDA, Innovation, Stagnation: Challenges and Opportunity on the Critical Path to New Medical Products

<sup>6</sup> G. A. Curt, and B. A. Chabner, One in Five Cancer Clinical Trials Is Published: A Terrible Symptom--What's the Diagnosis? *The Oncologist* 2008 13: 923-924

SAMPLE: SUPPORTING INFORMED PATIENT NAVIGATION  
AND DECISION MAKING

## Advancing the Routine and Informed Consideration of Clinical Trials



**ASK:** Doctor, for my diagnosis and clinical circumstance:

**What is the standard of care; and is it effective/curative?**  
**What clinical trials may be as appropriate?**

**Provider checklist:**

- \* Is my provider a lymphoma specialist, or a general oncologist?  
And is he or she aware of clinical trials?
- \* Have I consulted an independent expert about trials?
- \* Do all the providers I've consulted agree with the plan?

**Study considerations:**

- \* What are the competing protocols?
- \* What is the level of evidence so far?
- \* Am I eligible?
- \* Is travel or my insurance an obstacle?