Interest, attitudes, and participation in clinical trials among patients with lymphoma

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(with online access)

FINDINGS

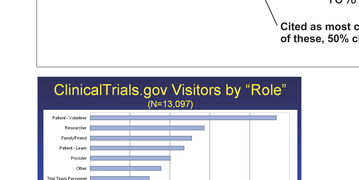
Population

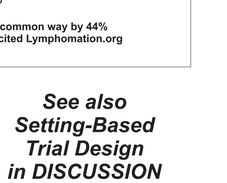
Survey participants: Lymphoma Patients and Caregivers with Web Access
Participants in Survey: 251 **Average Age** 51 **at diagnosis**

CONSIDERED TRIALS				HAVE NOT YET CONSIDERED TRIALS				OVERALL		
I've talked to a doctor about a study to treat my lymphoma, or I've seriously evaluated trials on my own - looked carefully at study protocol(s).				*I've never seriously evaluated a clinical trial as a possible treatment for my lymphoma.*						
By Gender and Cell Type:				**By Gender and Cell Type:**				**Overall**	**N**	**%**
Females	66	52%	.....	Females	88	70%	.....	.....	154	61%
Males	60	48%	.....	Males	37	30%	.....	.....	97	39%
Count	126		.....	Count	125		.....	.....	251	100%
Follicular	69	55%	.....	Follicular	48	38%	.....	.....	117	47%
DLBC	7	6%	.....	DLBC	25	20%	.....	.....	32	13%
CLL_SLL	17	13%	.....	CLL_SLL	12	10%	.....	.....	29	12%
MCL	10	8%	.....	MCL	7	6%	.....	.....	17	7%
MZL	11	9%	.....	MZL	22	18%	.....	.....	33	13%
Hodgkins	7	6%	.....	Hodgkins	2	2%	.....	.....	9	4%
T-cell	1	1%	.....	T- cell	1	1%	.....	.....	2	1%
Unknown	2	2%	.....	Unknown	4	3%	.....	.....	6	2%
Other	2	2%	.....	Other	4	3%	.....	.....	6	2%

Current Status and Participation in Clinical Trials

	# of Surveyed	Participated	Have Not	Participation %
Untreated	35	0	35	0%
In Treatment	43	18	25	42%
One Treatment	57	8	49	14%
One treatment and remission	34	4	30	12%
Watchful Waiting	45	5	40	11%
Active disease	32	16	16	50%
In Remission	117	19	98	16%





Instrument

We captured and analyzed the data using off-the-shelf products (HTML survey and spreadsheet).
The conditional survey design branched to one of two sets of questions depending on the participant's response to the following question:

I have considered clinical trials

I've talked to a doctor about a study to treat my lymphoma, or I've seriously evaluated trials on my own - looked carefully at study protocol(s).

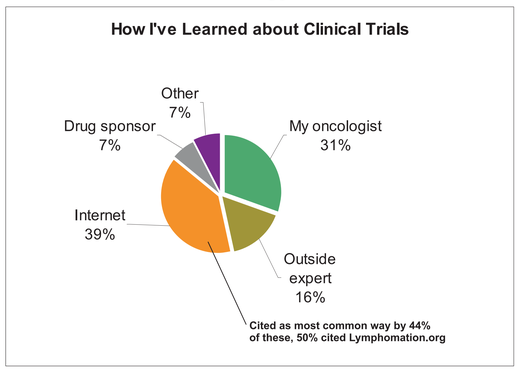
or

I have NOT yet considered a clinical trial

I've never seriously evaluated a clinical trial as a possible treatment for my lymphoma

See survey: www.Lymphomation.org/ps1.htm

Learning About

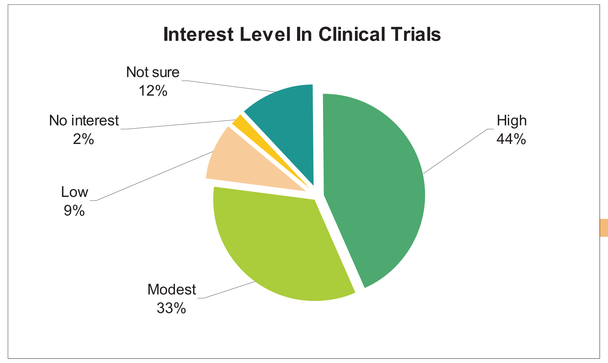


This ACSI data suggests that study protocols on Clinical Trials.gov should be written to facilitate understanding by patients and caregivers.

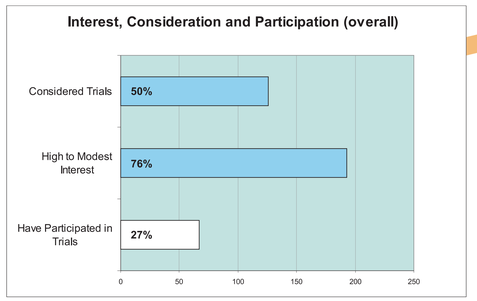
See also Setting-Based Trial Design in DISCUSSION

FINDINGS (continued)

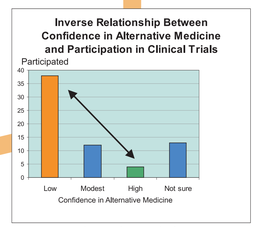
Interest and Participation



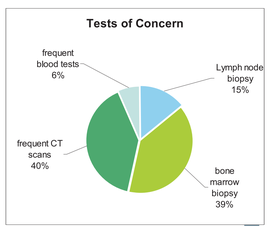
Patient attitudes towards trials are not the main obstacle to enrollment



Interest and participation rates higher than commonly cited (3-5%) in this cohort

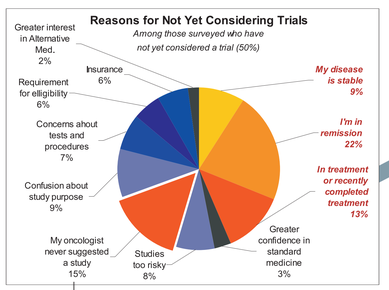


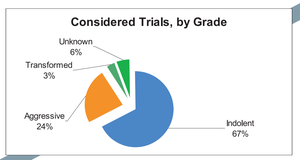
A reason to help patients judge plausibility of Alternative Medicine?



6% cited Procedures and Tests as a reason for declining to participate in a clinical trial.

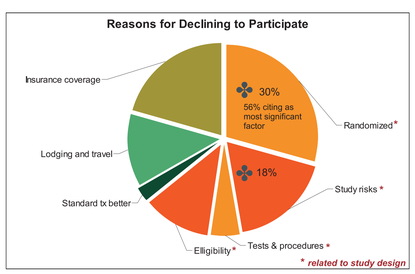
Considering Trials - or Not





"My oncologist never suggested a study"* main reason cited for not considering, *after treatment status

Reasons for Declining

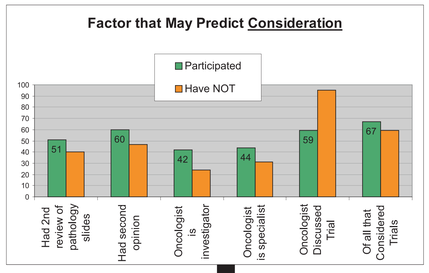


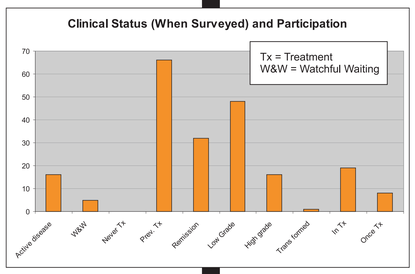
NOTE: At the time of this survey many patients with follicular lymphoma (this histology representing 47% of those surveyed) were considering participation in idiotype vaccine clinical trials and were concerned about being randomized to the placebo vaccine arm and receiving only CVP induction therapy as first primary treatment. Also, there was no expected benefit from the placebo vaccine in the patient community.

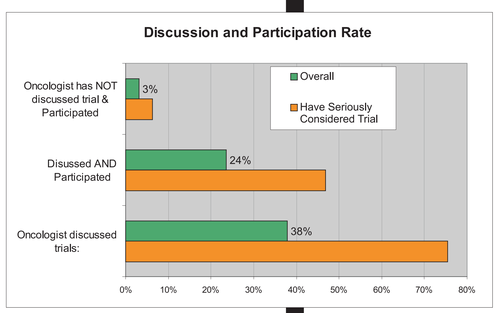
We believe this could account in part for the concern with randomization in this cohort, and anticipate that the level of concern with randomization will be study-specific.

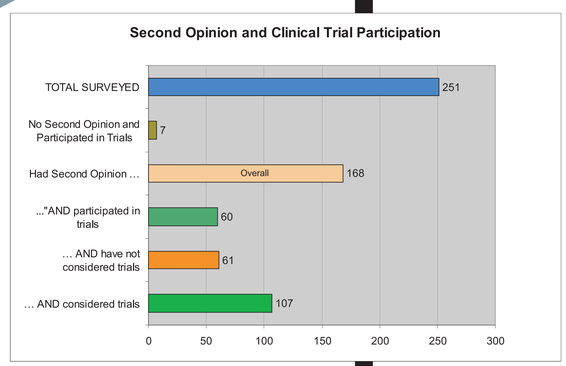
✤ Risk of Harm (Randomized + Study Risks: 48%)

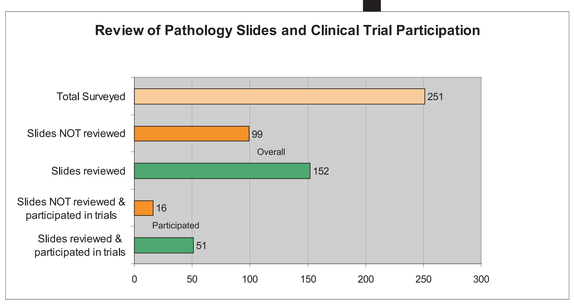
Associations with participation











SUMMARY

OBJECTIVES

To identify patient attitudes about clinical trials and factors that may predict interest and participation in order to inform future study design and improve the clinical trial referral system.

LIMITATIONS

This cohort was a non-random sample, restricted to online users. Subscribers to web-based support forums were the main participants.

Average age was 54 years, much younger than the mean for NHL, which is approximately 64 years at diagnosis. Only six % of survey participants had Hodgkin's lymphoma (average age, 28 years).

We cannot tell from this survey if the factors associated with interest and participation in clinical trials are related to clinical necessity (higher-risk disease) or that (online / younger) patients are more proactive, or are more likely to be eligible for studies.

We are considering applying an improved version of our survey to a random sample, pending feedback on this report and funding.

FINDINGS

Participation (27%) in clinical trials was much higher than expected. Commonly, 3-5% rates are cited among the general population with cancers.

Having Second Opinions, Second Evaluations of Pathology, and Consulting Outside Experts were all associated with higher participation and interest in clinical trials.

Having a Second Opinion had the highest association with consideration (107 of 168) and participation (58 of 107) in clinical trials.

We should be encouraged by the high rate of participation among those who have Discussed Studies with Outside Experts (62%) or their Oncologist (60%), which suggests that making the discussion of clinical trials a standard practice will increase enrollment rates.

The Internet was reported as the primary way patients learned about clinical trials.

We interpret concerns with Randomization (30%) as a *fear of receiving an inferior protocol* - a form of Study Risk. Therefore perceived risk (30% + 18%) is the primary reason for declining to participate in a *considered* clinical trial in this cohort.

For full report, see
www.Lymphomation.org/IAF-report.PDF

DISCUSSION

BACKGROUND

- Enrollment in clinical trials is widely acknowledged to be insufficient to support progress against cancers (3-5%).
- As drug discovery accelerates, the evaluation bottleneck will get worse:

  Thousands of new agents, instead of hundreds, but the same number of patients and the same un-adressed obstacles to enrollment, which are undoubtably delaying innovations.

ASSUMPTIONS

- Patients are risk-adverse; tend to delay treatment decisions, which favors use of familiar, standard protocols when they get sick or need therapy.
- To patients, participation in a clinical trial is a *treatment decision*.

  As such, study protocols must compare favorably to other studies and available standard therapies: be reasonable / appropriate treatment decisions for their clinical setting - and also readily available for consideration.

SETTING-BASED TRIAL DESIGN

- Rationales for participation - *based on potentially meeting clinical needs and treatment objectives in common clinical settings* - should be described clearly in *searchable fields* in study protocols posted to ClinicalTrials.gov - …

  … basing study designs on meeting needs and treatment goals for *ethical reasons*, with awareness also of patient biases and hopes for *practical reasons*.

  A few examples:

  a) Alternatives to expectant management (watch & wait):

  Agents and protocols with low / reversible / transient toxicity such as immunotherapy, or select targeted agents.

  b) First primary therapy:

  Head-to-head studies comparing frequently prescribed protocols where there's genuine uncertainty about which is superior. (CHOP-R versus CVP-R versus RIT for example)

  c) Refractory disease setting:

  Agents and protocols that may overcome drug resistance.

NEW TOOLS AND STANDARDS

- Biospecimen-based studies are needed to address patient and disease heterogeneity.

  Accounting better for biological and genetic variables could reduce risk, making clinical trials more attractive to patients and to their treating physicians than standard medicine.

STREAMLINE ENROLLMENT

- Refer patients to centers that can capture and store tissue that support biospecimen-based research.
- Make discussion of clinical trials common practice; utilize waiting room time, web-based videos …
- Raise awareness among patients that study participation can be an appropriate treatment decision.
- We might reward or provide national recognition to physicians who refer patients to clinical trials.
- We might form an independent committee (NCI/non-profit-based) to identify trials appropriate to different clinical settings in order to make study consideration more feasible for general oncologists and also to minimize risk to patients from sponsor or investigator bias.
- Finally, a guiding principle for patients and drug sponsors is SELF INTEREST.

  We each need incentives: Sponsors to innovate; patients to participate. The keys to progress and success include:

  ~ Fund and support the shared infrastructure and adoption of research standards;

  ~ Expedite biomarkers discovery and validation in order to make study participation safer - minimizing what patients fear most: unproductive toxicity, particularly of a type that burns treatment bridges;

  ~ Provide commercial incentives to develop and test targeted drugs on select patients. The orphan drug program as a possible model for personalized drug development;

  ~ Patients to contribute tissue and to enroll in trials (as research partners);

  ~ Study design that makes trial participation a smart treatment decision.

Mail inquires to:
Support@lymphomation.org

Abstract: P-0037

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