Cancer Research Advocacy

Jane Perlmutter | janep@gemini-grp.com

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1. Cancer Advocacy Landscape
2. Becoming an Excellent Advocate
3. The Drug Development Process & Basics of Clinical Trials
4. Things Patients Should Think about Clinical Trials
What You Should Remember About Patients/Advocates?

Many **Patients** Do Not Have The Luxury Of *Patience*

All Patients Are the Same

- Fearful
- Emotionally agitated
- Cognitively impaired

Each Patient Is Unique

- Values & Culture
- Family & Work
- Geography & Finances
From Patient to Research Advocate

Patients

• Cannot wait
• Often cannot advocate for themselves
• Often willing to take great risk for low probability of gain

Advocates

• On average, more interested and knowledgeable about science
• Want to ensure that research is efficient, effective and patient focused

Research Advocates

• Have a somewhat longer term perspective
• Want to prevent others from going through what they have
• Have a great diversity of knowledge, opinions and approaches
Types of Advocacy

- Fundraising
- Public Health Policy
- Education & Awareness
- Research
- Peer Support
Cancer Advocacy Timeline


ACS Founded
ACS Army of Women
ACS Reach to Recovery
NCCS Founded
DOD Cancer Funding
PCORI Founded

Education/Awareness
Fundraising
Peer Support
Public Policy
Research Advocacy
Why Involve Advocates in Research?

- Ensure patient focus
- Add a human face and sense of urgency
- Stimulate discussion
- Provide diverse perspective
- Spur innovation
- Expand public understanding of science

Types of Research Advocacy
## Example Activities

<table>
<thead>
<tr>
<th>Strata</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocating Research Funding</td>
<td>• Establishing research priorities, writing RFAs&lt;br&gt;• Participating in peer and programmatic review</td>
</tr>
<tr>
<td>Participating in Research Teams</td>
<td>• Providing input and feedback on grant applications, abstracts, and papers&lt;br&gt;• Participating in research group meetings&lt;br&gt;• Bridging gaps among stakeholders</td>
</tr>
<tr>
<td>Planning &amp; Implementing Clinical Trials</td>
<td>• Helping to design patient-centered trials&lt;br&gt;• Reviewing informed consents and patient support materials&lt;br&gt;• Providing patient navigation and peer support&lt;br&gt;• Helping recruit and support trial participants&lt;br&gt;• Being members of Institutional Review Boards (IRBs), Protocol Review Boards (PRBs) and Membership on Data Safety Monitoring Boards (DSMBs)&lt;br&gt;• Writing patient friendly summaries of results</td>
</tr>
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## Example Activities

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</table>
| **Translating & Disseminating Research** | • Attending advocacy and scientific meetings and training  
• Presenting at advocacy and scientific meetings  
• Planning advocacy and scientific meetings and training  
• Publishing in advocacy and scientific journals, websites, listserves and blogs  
• Conducting public outreach through national, regional and local organizations |
| **Research Policy & Oversight** | • Being members of Policy Committees, Clinical Practice Guideline Committees  
• Being involved in reengineering efforts  
• Engaging with FDA                                                                 |
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## Five Principles of Successful Collaboration

<table>
<thead>
<tr>
<th>Researchers Role</th>
<th>Advocates Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Provide meaningful opportunities throughout project</td>
<td>1. Be engaged &amp; provide meaningful input throughout project</td>
</tr>
<tr>
<td>2. Provide clear expectations &amp; accountabilities</td>
<td>2. Obtain clear expectations &amp; accountabilities</td>
</tr>
<tr>
<td>3. Utilize adequately trained advocates</td>
<td>3. Seek adequate &amp; continuing training</td>
</tr>
<tr>
<td>4. Provide opportunities for experienced &amp; novice advocates</td>
<td>4. Become both a mentee &amp; mentor</td>
</tr>
<tr>
<td>5. Compensate advocates as appropriate</td>
<td>5. Expect fair compensation; but be willing to volunteer</td>
</tr>
</tbody>
</table>
Getting Involved | Understand Who You Are

- Your passions
- How your non-cancer experiences can add to your advocacy
- Your strengths and weaknesses
Getting Involved | Understand Where You Can Best Contribute

- Start off opportunistically
- As you gain experience and a network, become more strategic

Types of Advocacy:
- Research Advocacy
- Fundraising
- Public Health Policy
- Education & Awareness
- Research
- Peer Support

Research Advocacy Opportunities:
1. Allocating of Research Funding
2. Participating in Research Teams
3. Planning & Implementation Clinical Trials
4. Translating & Disseminating Research
5. Research Policy & Oversight

Experience & Education
- Opportunities
- Number of Opportunities
Being an Excellent Advocate

- Ensure two-way communication with diverse patients
  - All patients are the same
  - Each patient is unique

- Learn about the relevant science, but don’t expect to become an expert
  - The disease
  - The research process
  - The “Key Opinion Leaders” (KOLs)

- Be comfortable and participate
  - Be professional
  - Ask questions
The Value of Asking Questions?

- It helps you learn and actively participate in the meeting
- It raises issues researchers may not have thought of, or be comfortable asking
- It opens up discussion among knowledgeable people who may have different opinions on the topic.
- It gives researchers practice at discussing research in ways that are understandable to the public, including patients
Advocacy Do’s & Don’ts

- Represent a variety of patient perspectives
- Ask questions about things you don’t understand
- Understand expectations about your involvement
- Ask for feedback
- Act professionally

- Focus exclusively on your experiences
- Ask questions about your cancer
- Expect to understand all of the science
- Expect all of your recommendations to be heeded
JP Advocacy Advice

- Be opportunistic when you are starting out; strategic later on
- Understand and adapt to the host’s culture (e.g., academic, for-profit)
- Clarify and meet (or exceed) expectations
- Seek feedback
- Keep learning
- Read broadly
- Push the envelope

Add Value!
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The Drug Development Process

- Thousands of compounds screened
- Preclinical Pharmacology
- Preclinical Safety
- Clinical Pharmacology & Safety

- Discovery
- Exploratory Development
- Full Development

- Phase I
- Phase II
- Phase III
- Phase IV

- Idea to Drug: 11 - 15 Years
- 1-2 Products

- Approximately 250
- Approximately 5
The Drug Development Process: Take-away Messages

- It takes a long time
- It is expensive
- There are many failures along the way

“I go home today. They cured me using this new miracle drug. I’m afraid it’ll be years before it’s approved for humans.”
What is a Clinical Trial?

- Research that carefully tests new ways to prevent, diagnose, or treat diseases
- A study that includes only patients who choose to participate
- An important way to advance science and develop better therapies for patients with diseases similar to those being treated in the trial
# Clinical Trial Phases

<table>
<thead>
<tr>
<th>Primary Goal</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Phase IV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Goal</strong></td>
<td>• Establish the overall safety</td>
<td>• Establish the activity of a drug for a specific group of patients with a specific disease</td>
<td>• Confirm the safety and effectiveness of a drug for a specific group of patients with a specific disease</td>
<td>• Monitor ongoing safety in large populations and uncontrolled use of drug</td>
</tr>
<tr>
<td><strong>Secondary Goals</strong></td>
<td>• Establish the maximum tolerated dose</td>
<td>• Determine the common short-term side effects and risks.</td>
<td>• Evaluate the overall risk-benefit ratio</td>
<td>• Identify additional, unusual side-effects</td>
</tr>
<tr>
<td></td>
<td>• Determine serious side-effects</td>
<td></td>
<td></td>
<td>• Identify additional potential uses of the drug</td>
</tr>
<tr>
<td></td>
<td>• Determine the metabolism and pharmacologic actions of drugs</td>
<td></td>
<td></td>
<td></td>
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</table>

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## Clinical Trial Phases

<table>
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<tr>
<th></th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Phase IV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Typical Number of Participants</strong></td>
<td>10 – 75</td>
<td>50 – 300</td>
<td>300 – 5,000</td>
<td>300 – 5,000</td>
</tr>
<tr>
<td><strong>Typical Number of Participating Institutions</strong></td>
<td>1</td>
<td>1 – 5</td>
<td>5 – 100</td>
<td>5 – 100</td>
</tr>
<tr>
<td><strong>Typical Length of Time to Complete</strong></td>
<td>1 – 6 months</td>
<td>6 months – 2 years</td>
<td>1 – 10 years</td>
<td>6 months – 5 years</td>
</tr>
<tr>
<td><strong>Typical Cost</strong></td>
<td>$100k -- $1m</td>
<td>$10m -- $100m</td>
<td>$10 -- $500m</td>
<td>$10 -- $100m per trial</td>
</tr>
</tbody>
</table>
Important Definitions

- **Placebo:** An inactive substance or treatment that looks the same as, and is given the same way as, an active drug or treatment being tested.

- **Standard of Care (SoC):** Treatment that experts agree is appropriate, and widely used. In cancer trials the control group generally receives SoC, rather than a placebo.

- **Investigational Agent:** Drug not yet approved for use in the patients outside of clinical trials.
Important Definitions

- **Experimental Group (or Arm):** A group of patients who receive an investigational intervention, often along with SoC.

- **Control Group (or Arm):** A group of patients who receive the SoC, sometime along with a placebo.

- **Randomization:** The process by which patients are assigned by chance to separate groups that compare different treatments.
- **Blinding:** Keeping information about which patients are in the experimental vs. control groups is hidden to reduce bias.

- **Crossover:** Allowing patients who do not respond to the treatment to which they were randomly assigned, to switch to the alternative treatment after some pre-specified amount of time.
Research Advocate Involvement Across the Clinical Trial Continuum

- **Develop Study Concept**
  - Provide information about unmet needs
  - Assess interest of patient community

- **Prepare Study Protocol**
  - Support discussions with funders, sites & IRBS
  - Support trial awareness & recruitment

- **Open Study Sites**
  - Provide feedback from patient community on sites, investigators, & study experience

- **Conduct Study**
  - Serve on Trial Steering & Data Monitoring Committees
  - Provide peer support during consenting

- **Analyze Data**
  - Provide FDA testimonies
  - Prepare lay summaries
  - Co-author papers & posters
  - Communicate with patient community

- **Disseminate Results**

- **FDA Review & Approval**

- **Prepare Study Protocol**
  - Provide input on study design
  - Assist in creating informed consent document & patient education material

- **Conduct Study**
  - Serve on Trial Steering & Data Monitoring Committees
  - Provide peer support during consenting

- **Analyze Data**
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  - Communicate with patient community
Input on Study Design | Maximizing Patient Benefit

- Power trials to achieve large benefits
- Limit eligibility requirements to those that impact patient safety
- Minimize number of patients who will receive placebo or standard of care (e.g. 2:1 randomization)
- Allow patient to continue on effective therapy beyond trial
- Allow patients in the control arm to cross-over
- Include PROs & QoL measures
- Return results (aggregate & individual) to participants
- Allow patients to donate their tissue & data for future research
Input on Study Design | Minimize Patient Burden

- Only include important research procedures & questionnaires
- Schedule appointments for patients’ convenience
- Be proactive about providing supportive care for toxicities
- Be mindful of direct & indirect financial consequences of Power trials to achieve large benefits
- Limit eligibility requirements to those that impact patient safety
Patient-Centric | From Start to Finish

1. **Design patient-centric trials**
   - Minimize patient burden
   - Maximize potential patient benefit

2. **Implement trials in a patient-centric manner**
   - Develop patient friendly informed consents and educational material
   - Train staff in patient communication

3. **Disseminate results to patients**
   - Overall findings
   - Individual results

Plain Language Summary
1. Cancer Advocacy Landscape
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## What are the Pros and Cons of Participating in a Clinical Trial?

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<thead>
<tr>
<th><strong>Pros</strong></th>
<th><strong>Cons</strong></th>
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</thead>
<tbody>
<tr>
<td>Treatment by a team of first rate clinicians at a comprehensive cancer center</td>
<td>Possible need to travel further for treatment</td>
</tr>
<tr>
<td>More, and possibly better, attention</td>
<td>Possibility of receiving a new drug that provides no additional benefit but may add side effects</td>
</tr>
<tr>
<td>Potential to receive a new, beneficial drug</td>
<td>Additional visits to the clinic and additional laboratory procedures</td>
</tr>
<tr>
<td>Opportunity to contribute to the advancement of science</td>
<td></td>
</tr>
</tbody>
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Considering Participating in a Clinical Trial?

Questions Patients Should Ask & Get Answered

- What is the study about?
- Who put the study together?
- Where is the trial being conducted?
- How long will the study last?

- What phase trial is it?
- Are patients randomized? If so, what treatment do patients in the control group receive?
- Is there crossover?
Considering Participating in a Clinical Trial?

More Questions Patients Should Ask & Get Answered

- What will I get out of the study?
- What are the risks? Side effect of investigational therapy?
- What tests are involved?
- What costs may be involved?
- What are the alternatives to this trial?
Barriers to Clinical Trial Participation

- **Patient Barriers**
  - Trial matching and navigation services
  - Informed consent documents and processes
  - Materials and resources for:
    - Just-in-time clinical trial education
    - Patient-facing decision support
  - Financial Toxicity

- **Trial-Design Barriers**
  - Unnecessary eligibility requirements
  - Randomization
  - Lack of cross-over
  - Too many, inconveniently scheduled incremental procedures

- **Advocate involvement in planning trials:**
  - Brings these issues to the forefront
  - Provides solutions

See: [ACS Barriers to CT Participation Report](#)
Final Thoughts | Advocacy Aphorisms

- Patients don’t have the luxury of patience (*JP*)
- I need my say; I don’t always need my way (*JP*)
- Aspire to be profound; being provocative and passionate also add value (*JP*)
- Under commit; over deliver (*JP*)
- Disagree; don’t be disagreeable (*Pat Gavin*)
- Less Hype; more hope (*Deb Collyar*)
- About me; with me (*AIDs Advocates*)
- Think about what is the matter with the patient, but also what matters to the patient (*Sandy Finestone*)
LINKS & RESOURCES
## Internet Resources

<table>
<thead>
<tr>
<th>Resource</th>
<th>URL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Google</td>
<td><a href="http://www.google.com">www.google.com</a></td>
</tr>
<tr>
<td>Wikopedia</td>
<td><a href="http://www.wikipedia.org">www.wikipedia.org</a></td>
</tr>
<tr>
<td>NCI Tutorials</td>
<td><a href="http://www.cancer.gov/cancer_topics/understandingcancer">http://www.cancer.gov/cancer_topics/understandingcancer</a></td>
</tr>
<tr>
<td>AACR Scientist ←→ Survivor Site</td>
<td><a href="http://www.aacr.org/home/survivors--advocates.aspx">http://www.aacr.org/home/survivors--advocates.aspx</a></td>
</tr>
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</table>
Online Learning Resources

- National Cancer Institute (NCI) Advocacy Relations and Training Material

- Research Advocacy Network (RAN)
  - [http://www.researchadvocacy.org](http://www.researchadvocacy.org)

- Cancer Information and Support Network (CISN)
  - [http://cisncancer.org](http://cisncancer.org)

- Food and Drug Administration (FDA)
  - [http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/ucm385535.htm](http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/ucm385535.htm)
Relevant Listservs and e-Scriptions

- Pair (Patient Advocates in Research)
- NCI Advocates
  - http://advocacy.cancer.gov/getinvolved/subscribe
- Cochrane Breast Cancer Reviews
  - http://breastcancer.cochrane.org
- ASCO Post
  - http://www.ascopost.com
Relevant Hardcopy Magazines

- Cure Magazine
  - http://www.curemagazine.com

- Cancer Today
  - http://www.cancertodaymag.org/Pages/default.aspx?gclid=C1ur29mvqb0CFRQV7AodJzUACw
Research Advocate Opportunities

- Local Advocacy Opportunities
- Federal Advocacy Opportunities
- Grant Review Opportunities
- Professional Meeting Scholarship Opportunities
Local Advocacy Organizations

- Bladder Cancer Advocacy Network
  - Survivor 2 Survivor & BCAN Connection
- Local Advocacy Organizations
- Local Institutional Review Boards (IRBs)
- Local Scientific Advisory Boards
- Local Hospital Volunteer Organizations
- American Cancer Society (ACS)
- Local Researchers
Federal Advocacy Opportunities

- National Cancer Institute (NCI) Advocacy Relations and Training Material
  - http://advocacy.cancer.gov/getinvolved/resources

- Food and Drug Administration (FDA) Advocate Opportunities
  - http://www.fda.gov/ForConsumers/byAudience/ForPatientAdvocates/

- Cochrane Reviewer
Grant Review Opportunities for Advocates

- American Cancer Society (ACS)

- Department of Defense’s (DOD’s) Cancer Research Program
  [http://cdmrp.army.mil/cwg/program_requirements](http://cdmrp.army.mil/cwg/program_requirements)

- Patient Centered Outcome Research Institute (PCORI)
Professional Meeting Scholarship Opportunities for Advocates

- Accelerating Anticancer Agents Development and Validations (AAADV) Workshop:
  - [https://www.acceleratingworkshop.org/2017/fundamentals/](https://www.acceleratingworkshop.org/2017/fundamentals/)
- American Association of Cancer Researchers:
  - [https://www.acceleratingworkshop.org/2017/fundamentals/](https://www.acceleratingworkshop.org/2017/fundamentals/)
- American Society for Clinical Oncology Advocate (ASCO):
  - [http://am.asco.org/attend-meeting-patient-advocate](http://am.asco.org/attend-meeting-patient-advocate)
- Cancer Survivorship Biennial Conference:
- San Antonio Breast Cancer Symposium (SABCS):