BCAN®

Bladder Cancer Advocacy Network

Cancer Research Advocacy

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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

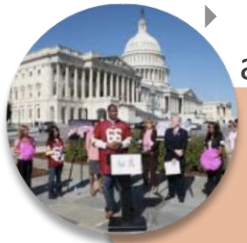
- Values & Culture
- Family & Work
- Geography & Finances

From Patient to Research Advocate

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

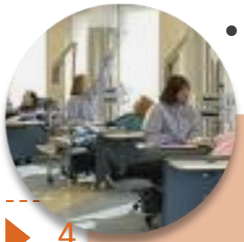
Research Advocates

- 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



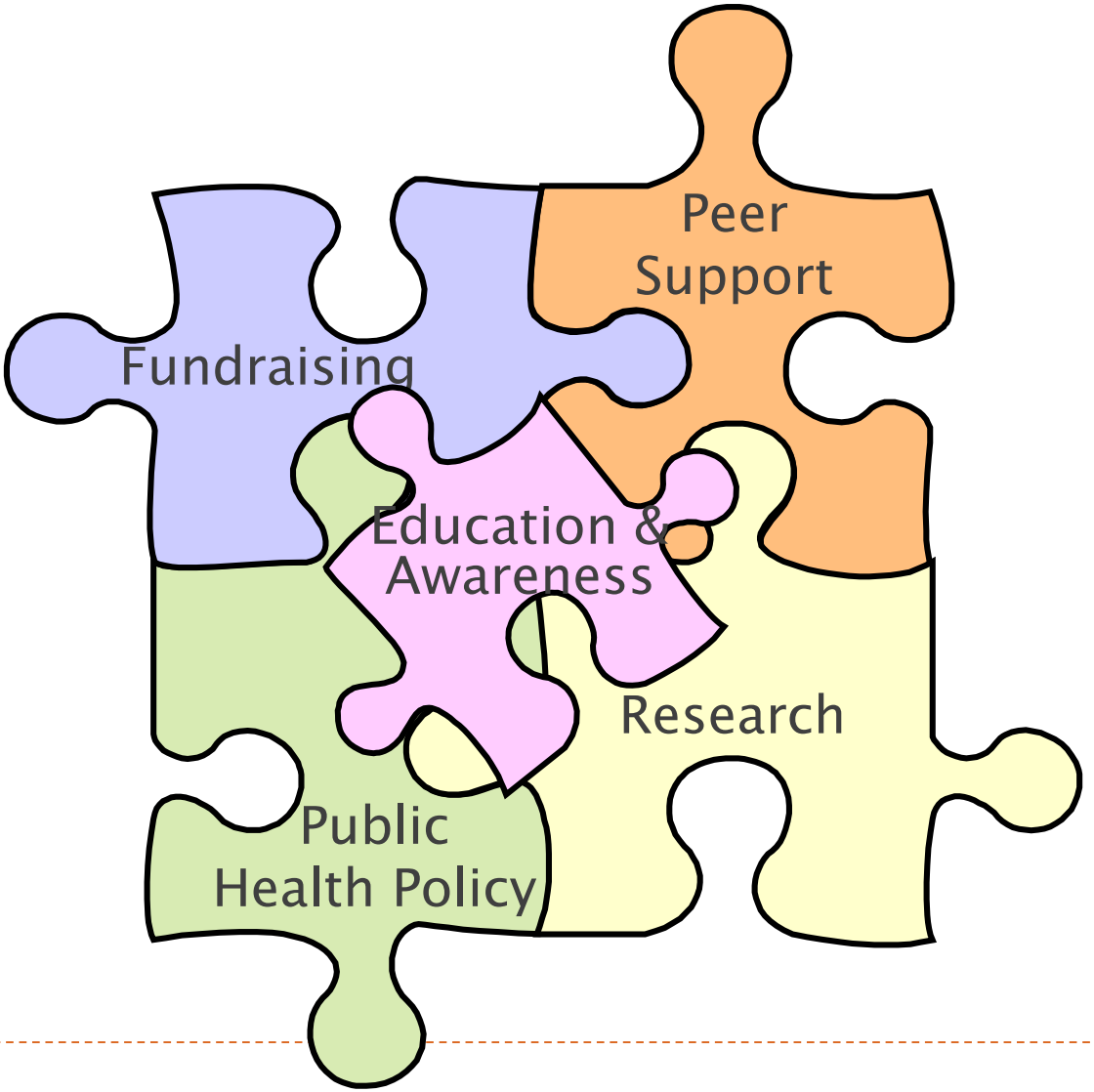
Advocates

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

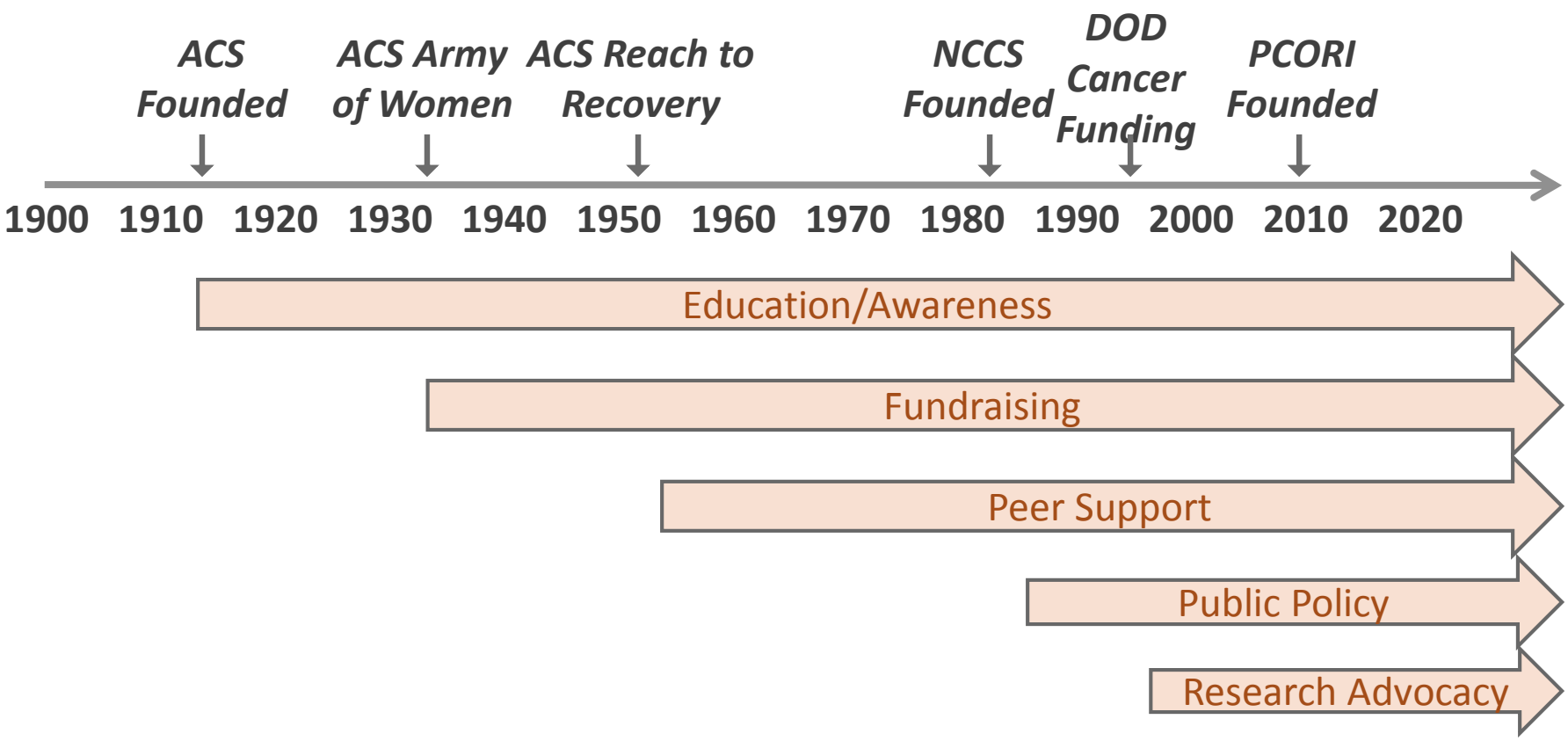


Patients

Types of Advocacy



Cancer Advocacy Timeline



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

From: Perlmutter J, Bell SK and Darien G. Cancer Research Advocacy: Past Present and Future. Cancer Research, 73(15), 2014, 4611-15.

Types of Research Advocacy

Example Activities

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

Example Activities

Strata	Activities
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

Researchers Role

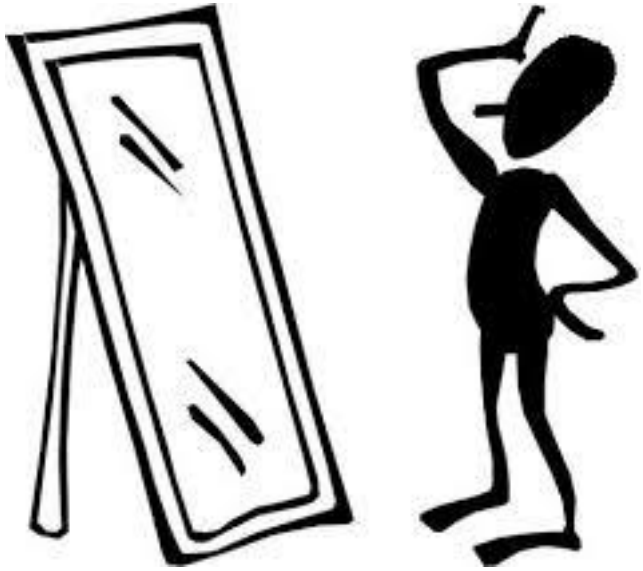
1. Provide meaningful opportunities throughout project
2. Provide clear expectations & accountabilities
3. Utilize adequately trained advocates
4. Provide opportunities for experienced & novice advocates
5. Compensate advocates as appropriate

Advocates Role

1. Be engaged & provide meaningful input throughout project
2. Obtain clear expectations & accountabilities
3. Seek adequate & continuing training
4. Become both a mentee & mentor
5. Expect fair compensation; but be willing to volunteer

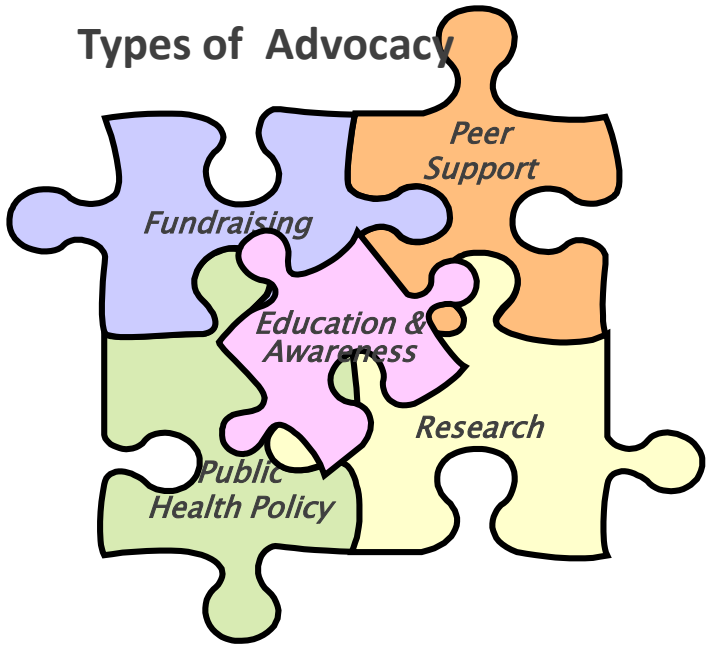
Getting Involved | Understand Who You Are

- Your passions
- How your non-cancer experiences can add to your advocacy
- You 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



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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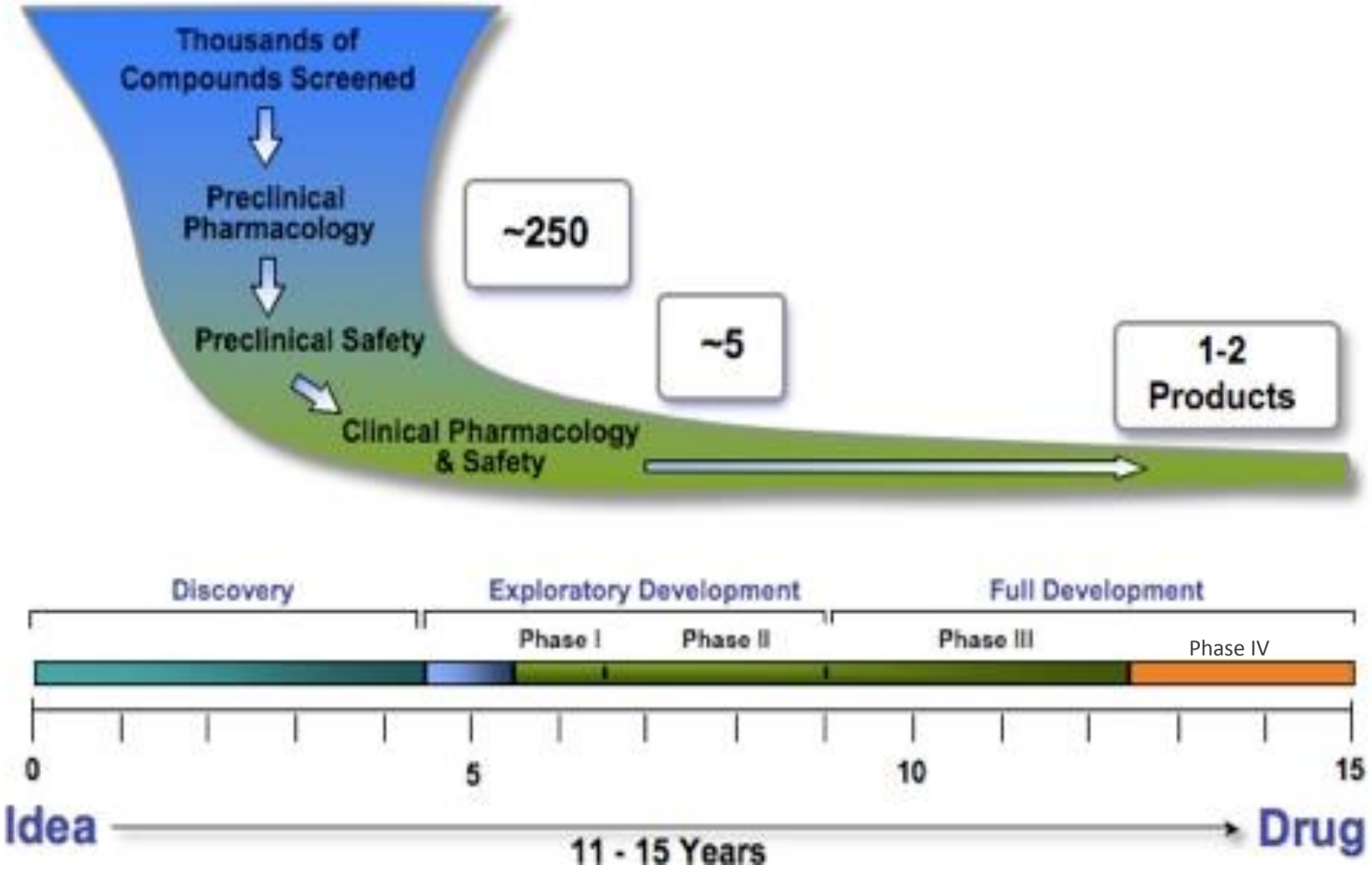
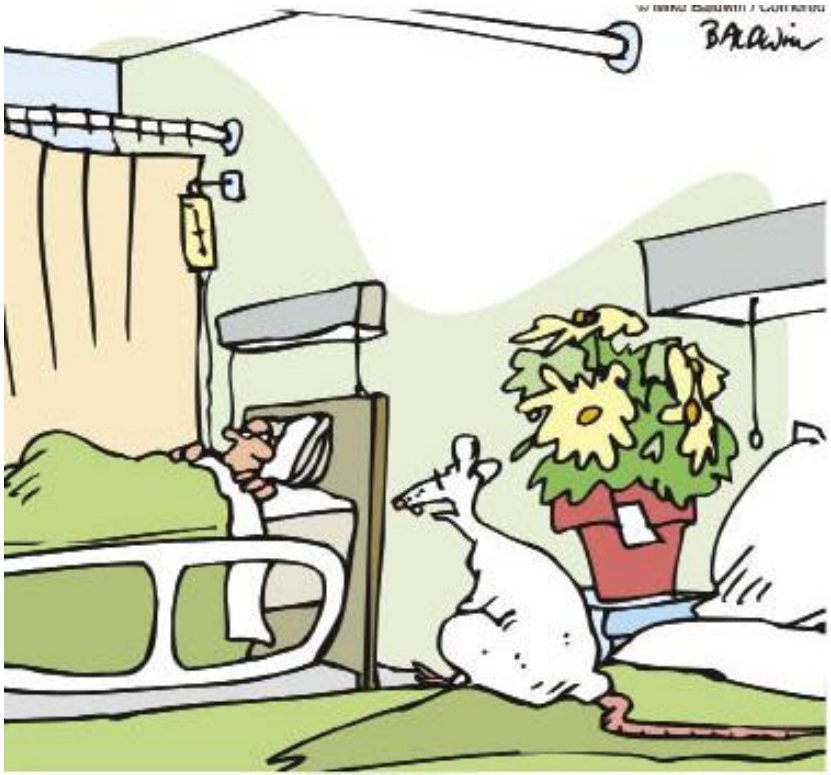
The Drug Development Process



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

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

Clinical Trial Phases

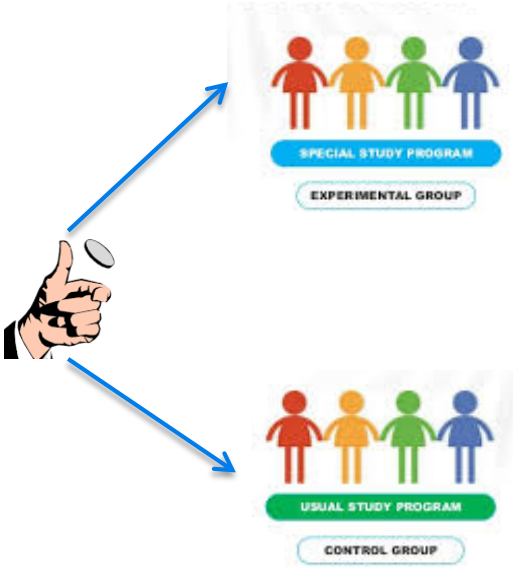
	Phase I	Phase II	Phase III	Phase IV
Typical Number of Participants	10 – 75	50 – 300	300 – 5,000	300 – 5,000
Typical Number of Participating Institutions	1	1 – 5	5 – 100	5 – 100
Typical Length of Time to Complete	1 – 6 months	6 months – 2 years	1 – 10 years	6 months – 5 years
Typical Cost	$100k -- $1m	$10m --$100m	$10 -- $500m	$10 -- $100m per trial

Important Definitions

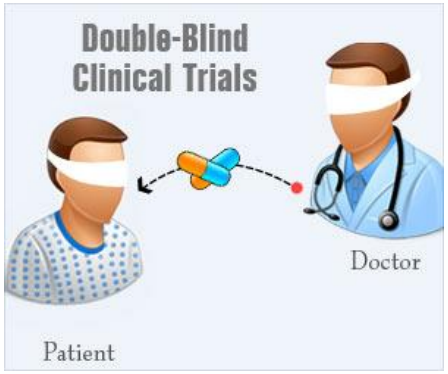
- ***Placebo:*** An inactive substance or treatment that looks the same as, and is given the same way as, an active drug or treatment being tested.
- ***Standard of Care (SoC):*** Treatment that experts agree is appropriate, and widely used. In cancer trials the control group generally receives SoC, rather than a placebo
- ***Investigational Agent:*** Drug not yet approved for use in the patients outside of clinical trials

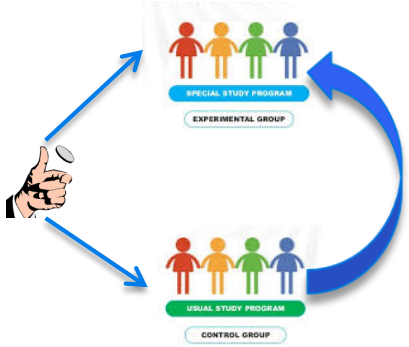
Important Definitions

- ***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

- Provide information about unmet needs
- Assess interest of patient community

- Support discussions with funders, sites & IRBS
- Support trial awareness & recruitment

- Provide feedback from patient community on sites, investigators, & study experience

- Serve on FDA advisory & post-market surveillance committees
- Provide FDA Testimony

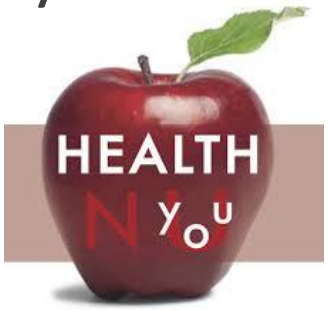
- Provide input on study design
- Assist in creating informed consent document & patient education material

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

- Prepare lay summaries
- Co-author papers & posters
- 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

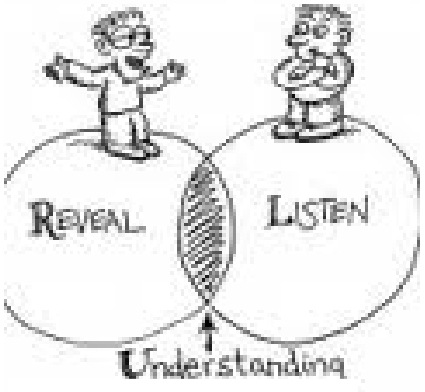


Input on Study Design | Minimize Patient Burden

- 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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What are the Pros and Cons of Participating in a Clinical Trial?

Pros

- Treatment by a team of first rate clinicians at a comprehensive cancer center
- More, and possibly better, attention
- Potential to receive a new, beneficial drug
- Opportunity to contribute to the advancement of science

Cons

- Possible need to travel further for treatment
- Possibility of receiving a new drug that provides no additional benefit but may add side effects
- Additional visits to the clinic and additional laboratory procedures

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

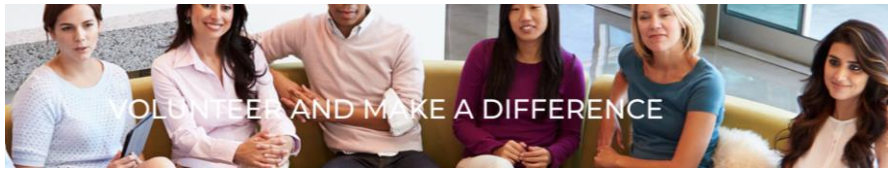
- What will the I get out of the study?
- What are the risks? Side effect of investigational therapy?
- What tests are involved?
- What costs may be involved?
- What are the alternatives to this tri

• • •

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
- ***Disparities***

- ***Advocate involvement in planning trials:***
  - Brings these issue 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

Resource	URL
Google	www.google.com
Wikopedia	www.wikipedia.org
NCI Tutorials	http://www.cancer.gov/cancertopics/understandingcancer
AACR Scientist ←→ Survivor Site	http://www.aacr.org/home/survivors--advocates.aspx

Online Learning Resources

- National Cancer Institute (NCI) Advocacy Relations and Training Material
  - http://www.cancer.gov/cancertopics/understandingcancer/cancer
  - https://pubs.cancer.gov/ncipl/home.aspx?js=1
- Research Advocacy Network (RAN)
  - http://www.researchadvocacy.org
- Cancer Information and Support Network (CISN)
  - http://cisncancer.org
- Food and Drug Administration (FDA)
  - http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/ucm385535.htm

Relevant Listservs and e-Scriptions

- Pair (Patient Advocates in Research)
  - http://listserv.acor.org/scripts/wa-ACOR.exe?SUBED1=PAIR&A=1
- 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=CIur29mvqb0CFRQV7AodJzUACw

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
  - 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)
  http://pressroom.cancer.org/Stakeholder2016
- Department of Defense's (DOD's) Cancer Research Program
  http://cdmrp.army.mil/cwg/program_requirements
- Patient Centered Outcome Research Institute (PCORI)
  http://www.pcori.org/get-involved/reviewers/

Professional Meeting Scholarship Opportunities for Advocates

- Accelerating Anticancer Agents Development and Validations (AAADV) Workshop:
  - https://www.acceleratingworkshop.org/2017/fundamentals/
- American Association of Cancer Researchers:
  - https://www.acceleratingworkshop.org/2017/fundamentals/
- American Society for Clinical Oncology Advocate (ASCO): http://am.asco.org/attend-meeting-patient-advocate
- Cancer Survivorship Biennial Conference:
  - http://www.cancer.org/subsites/survivorship2014/survivorship-2014-advocate-program
- San Antonio Breast Cancer Symposium (SABCS):
  - http://sabcs.org/PatientAdvocates/index.asp