



FDA's Clinical Investigator Course

A Patient Advocate's Perspective on Clinical Trials

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U.S. Department of Health and Human Services

Food and Drug Administration





Background

- BS Chemistry, MS Chemical Engineering
- 10 years - Consumer Goods Industry
- Consultant - Change Management in Mfg. and Utilities
- **Diagnosed Stage IIIB breast cancer in 1990**
- **Phase 2 clinical trial participant**
- EVP - National Breast Cancer Coalition
- Worked for Director, National Cancer Institute
- Consultant to Not for Profits, Government and Pharmas/Biotechs
- Currently - Executive Director, Reagan-Udall Foundation for the FDA



Physician as Patient - Richard J. Boxer, MD

“I survive because of those who came before me. I live because of the research performed by others, often funded by the generosity of the American people. But the generosity is beyond their tax dollars supporting research; I live because others participated in clinical trials that may not have helped them. By volunteering for clinical research, they helped push back the unknown and shed light upon the darkness of the undiscovered.”



Experience on a Clinical Trials

Participated in a Treatment Clinical Trial in 1990

- National Cancer Institute Intramural Program
- Phase II Dosing Trial for Stages IIIB, IV Breast Cancer
- Drugs –
 - 5-FU (fluorouracil)
 - Leucovorin
 - Doxorubicin (Adriamycin)
 - Cyclophosphamide (Cytosan)
 - GM-CSF (19 of 21 nights per round)

Participated in Genetic Counseling Trial 2004 – BrCa 2



Positives and Negatives of Participating in a Clinical Trial

Positives

- Get more information
- Better sense of control
- Attention to supportive care
- Get latest treatment or thinking
- Feel that you are doing something to help others

Negatives

- Risks - No data on efficacy of your treatment
- More tests than in standard care
- Being an “interesting patient” at the NIH
- No long term follow-up



Barriers to Patients Participating in Clinical Trials

Knowing Clinical Trials are Option, then Finding One

- Build it and they will come? (Most Patients don't know clinical trials or [clinicaltrials.gov](https://www.clinicaltrials.gov) exists)
- Logistics of getting to the right trial

Trust

- Will I just be a guinea pig?
- Will I get a placebo?
- Not being treated by “my doctor”
- Not everyone trusts the federal government (Tuskegee) or the pharma industry



Barriers to Patients Participating in Clinical Trials

Patient Values/Preferences/Capacity

- Personal perception of risk
- Popular Press - Expectations
- Randomization
- Patient care costs
- Additional tests/visits to the doctor
- Too much new info to process
- Too many options in time of crisis

■ ■ ■ Patient Accrual and Retention

To accrue and retain patients on clinical trials, more personal navigation and context is required

- Making the “decision of your life” requires personal contact and assurance
- Help setting up appointments and getting records to trial sites to be considered
- Understanding
- Assistance understanding what the choices will mean for their life and how to evaluate them



Patients vs. Patient Advocacy Groups



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How have Patient Advocates impacted the Drug Development Process?



Drug Development Process

The Drug Development and Approval Process								
It takes 15 years on average for an experimental drug to travel from the lab to U.S. patients. Only five in 5,000 compounds that enter preclinical testing make it to human testing. One of these five tested in people is approved.								
	Early Research /Preclinical Testing	File IND at FDA	Clinical Trials			File NDA at FDA	FDA	Dissemination to Physicians and Patients
Years	6.5		Phase I	Phase II	Phase III		1.5	15
Test Population	Laboratory and animal studies		20 to 80 patient volunteers	100 to 300 patient volunteers	1000 to 3000 patient volunteers		Review process/ approval	Knowledge of new treatment , reimbursement, and incorporation into their practice
Purpose	Assess Safety and biological activity		Determine safety and dosage	Evaluate effectiveness, look for side effects	Confirm effectiveness, monitor adverse reactions from long-term use			
Success Rate	5,000 compounds evaluated		5 enter trials				1 approved	1 treatment being used



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Why include Patient Advocates in the Research Process?

Participation of patient advocates can:

- Ensure that goals of patients are kept in the forefront
- Help make your trial design more patient friendly
- Improve patient accrual and retention
- Provide credibility that research is conducted in an inclusive, representative, and transparent manner



Thank You!

For dedicating your careers to
clinical research



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