Building a Patient Network

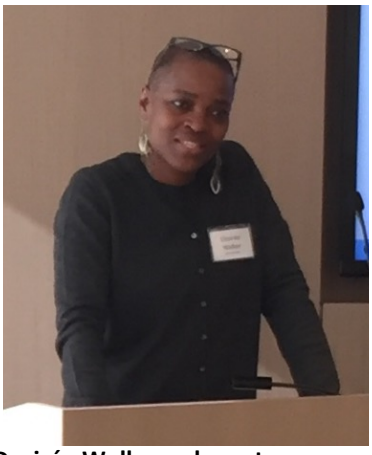
www.USAPatientNetwork.org

Thank you for participating in our November 13-14, 2015 workshop. Here is a summary of the workshop and our aims for the project.

Thirty-one patients, caregivers, and their advocates were selected to learn more about the types of research that can determine the safety and effectiveness of drugs and medical devices.

The **goal** was to increase their understanding of research issues so that they could be:

- better informed participants at public meetings,
- more likely to express their perspectives when the opportunity arose for written or oral statements or comments, and
- more likely to participate in opportunities that would strengthen the patient voice in medical research conducted or used by federal agencies, university researchers, and nonprofit organizations.



Desirée Walker, a breast cancer survivor and patient advocate, kicked things off with a motivational talk on how she became a patient advocate.

The November workshop was the second of four introductory workshops that the National Center for Health Research developed to build a network of patients who can work together to improve the safety and effectiveness of treatments. An advanced workshop will be held in June 2016 and will offer additional training to network members that participated in one of the first two workshops.

How did we do?

At the beginning and end of the workshop, everyone answered questions to help us determine how much the participants knew before and how much they learned during the workshop. Good news! Results show that participants were significantly more knowledgeable at the end of the workshop compared to the beginning.

What did participants learn the most? Before the Workshop, 40-60% did not know about:

- the difference between FDA standards for medical devices and prescription drugs,
- the definition of a p-value,
- the advantage of using biomarkers in clinical trials**,** and
- what a subgroup analysis is**.**

More than 90% of the participants knew what double blind clinical trials were prior to the Workshop, so there was less room for learning on that subject.

The questionnaires were very useful for identifying how we can improve the workshops. We will need to clarify our explanation of the criteria used for FDA approval, because overall the scores went down on this question after attending the workshop. We will also need to improve our training about the different types of clinical trials for future workshops.

Here are the results. **Comparisons in shaded boxes were statistically significantly different after the Workshop compared to before**.

Question	Friday Answers (% Correct)	Saturday Answers (% Correct)
Q#1 Criteria for FDA drug approval	77%	58%
Q#2 Drug vs. device standards	45%	84%
Q#3 Define p-value	61%	97%
Q#4 Define double-blind clinical trials	94%	100%
Q#5 Define randomized, controlled trial	48%	48%
Q#6 Define biomarkers or surrogate endpoints	77%	90%
Q#7 Advantages of studying biomarkers	45%	81%
Q#8 What is a subgroup	52%	94%
Q#9 Differences between pre- and post-market studies (there was more than one right answer, so each option was scored separately)	A. 74%	71%
	B. 74%	97%
	C. 35%	58%
	D. 84%	94%
	E. 55%	61%
Q#10 Define statistical significance (there was more than one right answer, so each option was scored separately)	A. 81%	90%
	B. 58%	61%
	C. 87%	97%
	D. 81%	97%
	E. 45%	68%

Comparisons in shaded boxes were statistically significant.

We also included open-ended questions and asked participants to express their opinions. There were no right or wrong answers, but after the Workshop, participants were able to give more thoughtful and informed opinions on topics such as direct to consumer advertising and the FDA approval process.

Participants' Evaluation of Workshop

Participants were also asked to evaluate all the speakers and the Workshop as a whole on a 5-point scale, with 5 signifying very interesting or helpful. Participants reported it was important to learn about FDA and said this goal was achieved. They said they appreciated the high level of interaction and lively discussion. They said hearing personal stories from other participants was "powerful," "heartfelt" and "moving." They enjoyed having "real world" examples from patient advocates such as Desirée Walker and Tim Horn, watching videos of patients testifying at FDA public meetings, and role playing to practice the skills they learned.

	Workshop Sessions	**Average** (Range)
Friday Nov. 13, 2015	1. **Patient Advocacy,** Desirée Walker, a breast cancer survivor	**4.8** (3-5)
	2. **Introduction to the FDA Approval Process,** NCHR's Dr. Diana Zuckerman	**4.8** (4-5)
	3. **Consumers Union and the Safe Patient Project**, Victoria Burack from Consumers Union and two Workshop participants from Safe Patient Project, Rex Johnson & Linda Radach	**4.3** (2-5)
	4. **Engaging Patients in Research,** PCORI's Michelle Johnston-Fleece	**4.4** (2-5)
	5. **Patient Panel Discussion** featuring Jeremy Lew, Katherine Leon, and Kim Meyers	**4.5** (3-5)
	6. **How to Become an FDA Patient Representative,** Andrea C. Furia-Helms and Salina Prasad, both of the FDA	**4.0** (2-5)
	7. **Insider's View of Patient Advocacy and the FDA,** Dr. Susan Wood (former FDA Assoc Commissioner)	**4.6** (3-5)
Saturday Nov. 14, 2015	1. **Introduction to Research,** NCHR's Margaret Dayhoff-Brannigan	**4.5** (3-5)
	2. **Subgroup Analysis,** NCHR's Laurén Doamekpor	**4.7** (4-5)
	3. **The Importance of Patient Advocates,** Tim Horn from Treatment Action Group, and Dr. Susan Molchan from National Physicians Alliance	**4.5** (3-5)
	4. **Opportunities for Patient Engagement**, NCHR's Paul Brown and Dr. Tracy Rupp	**4.6** (3-5)
	5. **Videos of Patient Advocates and Role Playing Exercise** led by NCHR staff.	**4.7** (2-5)

Overall, participants said they felt engaged and empowered, with 92% reporting that they would like to be involved in opportunities to provide patient perspectives at public meetings or in written comments.

What participants said we did well:

- Explained clearly the role of the FDA and its approval process for new drugs and devices.
- Answered questions with specific and appropriate detail; overall the instruction was very good.
- Facilitated engaging discussions and Q&A sessions with the experts.
- Encouraged collaboration between advocacy groups – many participants expressed interest in continued support from NCHR.

Examples of comments from participants:

Participant A: *"After this workshop, I feel that I am on my way to being better informed about scientific studies and I have some ideas about which organizations and individuals to contact and work with in our advocacy efforts."*

Participant B: *"This was a great workshop: Inspiring for me as a beginning advocate."*

Participant C: *"Thank you for inviting me to participate in this workshop. This was enormously beneficial to the advocacy work I'm involved with, and will help me advise others. 10 out of 10!"*

What we can improve next time:

- Make sure that everyone gets a chance to ask questions (some participants dominated the Q & A, which left less time for others). Improve the microphone usage to prevent it from being distracting and disrupting the flow.
- Encourage participants to ask fewer questions specific to personal issues, and more that the general group would benefit from.
- Provide bios and photos of each of the participants so it would be easier to get to know everyone.
- Provide more in-depth information "about what we can actually do and how to do it."
- Provide more specific examples of where advocacy has made a difference and what else patients can do.

Current Advocacy Activities

We asked participants to rank their willingness to participate in future opportunities to share their patient perspectives on a national level, on a scale of 1-5, with 5 being "very likely to participate" and 1 being they would "never consider participating." All participants expressed a desire to participate in some form, with almost all participants responding with a 4 or 5 on multiple parts of the question. In the months since the workshop, several participants have already signed up for FDA meetings, and signed on to letters or public comments that NCHR staff drafted in response to FDA's requests for comments.

What we've done since the Workshop:

- Formed a Patient Network list serv to help everyone stay involved.
- Launched a Patient Network Website (www.USAPatientNetwork.org).
- Created a Facebook page (Facebook.com/USAPatientNetwork).
- Created a Twitter page (Twitter.com/Patient_Network).
- Sent out monthly newsletters with current events and highlights of members' involvement.

What we're working on:

- Developing a toolbox including links and tutorials to get patient partners more engaged.
- Adding content to our Facebook and Twitter pages.
- Planning our June 2016 Advanced Training Workshop.

The USA Patient Network has been actively involved in public comments. We plan to continue to encourage involvement of our members in issues important to patients. Three organizations represented by network members have joined the Patient, Consumer, and Public Health Coalition, and have participated in written public comments to the FDA, signing on those comments on behalf of their affiliated patient organizations. Several members have reached out to NCHR for help on issues related to unsafe medical products, or for advice concerning testimony for upcoming advisory committee meetings.

Patient advocates working together

Participants are always welcome to reach out to NCHR with any questions regarding FDA, drugs, medical devices, etc. Please email Margaret (mdb@center4research.org) if you need anything.