Advanced Patient Training Workshop

Washington, DC
June 3-4, 2016

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Thank you to those who participated in our June 2016 Advanced Workshop! It was an exciting weekend of collaboration and learning. We heard from many of our patient partners about where they want the Network to focus its attention, and we are following up with as many of them as possible. We want to hear from you!

Twenty-six USA Patient Network members came together to learn and share ideas aimed at adding the patient perspective to medical research design and analysis. The Advanced Patient Training Workshop was led by staff of the National Center for Health Research (NCHR) and guest speakers including Tom Burton (Pulitzer Prize winning journalist for the *Wall Street Journal* who writes about the risks and benefits of medical products), Salina Prasad and Andrea Furia-Helms (who answered questions on behalf of the FDA patient representative program), and Desirée Walker (who talked about being a patient advocate).

Advocates learned about good research designs; the FDA approval process; the importance of including women, men, people of color, and people over 65 in clinical trials; how to find out about clinical trials; options for desperate patients who are not eligible for any clinical trials; and how to scrutinize and question the information provided on TV drug commercials. Short lectures were combined with small group discussions.

Desirée Walker, a breast cancer survivor and patient advocate, gave a motivational talk on how she became a patient advocate.

The highlight for many participants was our mock FDA Advisory Committee meeting. Two NCHR staff members presented an abbreviated version of the slide presentations from a real FDA meeting that reviewed the risks and benefits of Belsomra (a sleeping pill that FDA subsequently approved and is now widely advertised on TV). Workshop participants took on the role of Committee members and public comment speakers, in favor of or opposed to the drug. This interactive learning experience gave participants an opportunity to test their skills and gain confidence asking key questions at FDA meetings.

Small group discussions of the material led by NCHR staff

This is the only advanced workshop we have planned; however if you missed the workshop, stay tuned for webinars of the material presented. We will have another Introductory Workshop in the Fall, October 14-15, 2016. If you know any patient partners that would be interested in attending, please email info@USAPatientNetwork.org.

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 learned a lot during the event.

Based on feedback from the earlier Introductory Workshops, we modified our curriculum to include more small-group discussion and real world examples of the material. Everyone really enjoyed this style of learning, and it was clear from the questionnaire that it was also an effective teaching method!

Since it was an Advanced Workshop, most participants already knew the answers to most questions before the workshop. Before the workshop started, 10 of the 18 questions were answered correctly by more than 60% of the participants. In fact, 3 questions were answered correctly by 90% of the participants. After the workshop, half the questions were answered correctly by at least 80% of the participants! The learning was obvious from the complicated questions participants asked during the Workshop.

Here are the results. **Comparisons in shaded boxes were statistically significantly different after the Workshop compared to before**. As you can see, questions that were answered correctly on Friday were unlikely to show statistically significant changes, even though the percentage of correct answers increased.

Question	Friday Answers (% Correct)	Saturday Answers (% Correct)
Q#1 Criteria for FDA drug approval	62%	81%
Q#2 Drug vs. device standards	62%	88%
Q#3 Matching clinical trial types	1. 58%	77%
	2. 92%	100%
	3. 65%	85%
Q#4 Define biomarkers or surrogate endpoints	73%	85%
Q#5 Why is subgroup important	96%	100%
Q#6 Advantages of studying biomarkers	50%	73%
Q#7 Differences between pre- and post-market studies	A. 35%	42%
	B. 31%	31%
	C. 27%	35%
	D. 50%	50%
Q#8 T/F Advisory Committees	88%	80%
Q#9 Define statistical significance	A. 81%	88%
	B. 92%	92%
	C. 62%	73%
	D. 54%	46%
Q#10 Expanded access	15%	58%

The one question that did not improve was about the differences between pre-market and post-market studies.

We also asked participants to identify three potential questions to ask their doctors about participation in clinical trials. Overall, everyone showed a strong understanding of the types of questions that help ensure that they can make an informed choice about clinical trial participation.

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. The workshop and speakers as a whole were rated very highly. Participants reported that they learned valuable information from this workshop that they felt should be taught to everyone. Participants benefited from the small group activities and appreciated the high level of interaction and lively discussion. They thoroughly enjoyed participating in the "Mock FDA Advisory Committee Meeting" and felt it was an excellent learning tool that gave them an understanding of issues that may arise at a real meeting.

	Workshop Session	**Average** (Range)
Friday June 3, 2016	1. Advertising medical products on TV, by NCHR's Diana Zuckerman	**4.64** (3-5)
	2. FDA Standards by NCHR's Diana Zuckerman.	**4.60** (3-5)
	3. Desirée Walker, a breast cancer survivor and Patient Advocate.	**4.83** (4-5)
	4. Good Research by NCHR's Margaret Dayhoff-Brannigan, Training and small group discussion	**4.64** (4-5)
	5. FDA opportunities for Patient engagement Q&A by Andrea C. Furia-Helms and Salina Prasad, both of the FDA.	**4.16** (2-5)
	6. Reporters and Patients by Tom Burton, Wall Street Journal	**4.52** (3-5)
Saturday June. 4, 2016	1. Will this treatment work for me by NCHR's Miara Jeffress, Training and small group discussion	**4.62** (3-5)
	2. MOCK FDA Advisory Committee	**4.88** (4-5)
	3. Clinical Trials by NCHR's Tracy Rupp	**4.46** (1-5)
	4. Vision for the USA Patient Network	**4.64** (4-5)
Overall	Speakers/Moderators as a whole?	**4.79** (4-5)
	Workshop as a whole?	**4.79** (3-5)

Overall, participants said they felt engaged and empowered, and everyone said that they would like to continue to be involved with the Patient Network.

What participants said we did well:

- Provided detailed explanations on the FDA approval process for new drugs and devices.
- Answered questions with specific and appropriate detail; overall the instruction was very good.
- Facilitated interactive and engaging small group activities, 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: *"Thank you for the opportunity to learn more about a variety of patient experiences! Very thoughtfully organized conference with lots of useful material."*

Participant B: *"All speakers offered a lot of good expertise. I thoroughly enjoyed both days and feel like I learned a lot."*

Participant C: *"Thank you for your leadership, vision, clarifying info, and network of support."*

What we can improve next time:

- Provide handouts on how the FDA approval process works and how to become involved with the FDA.
- 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 invited participants to join our list serv and mailing list for the monthly newsletter. We have also posted all of the materials from the workshop on the Patient Network website under the tools section (www.USAPatientNetwork.org). We are reviewing footage from the workshop for editing into a series of webinars for use on our website to train participants that were unable to attend the workshop. We are also developing additional content for our website in response to requests from patient partners at the meeting.

In the weeks after the Advanced Training Workshop, the USA Patient Network members sent an email letter to Salina Prasad and Andrea Furia-Helms, from the FDA Patient Representative Program, to reiterate our request that the FDA make patient safety a priority.

What we're working on:

- Developing a toolbox including links and tutorials to get patient partners more engaged.
- Creating webinars from the video footage taken at the Workshop.
- Adding content to our Facebook and Twitter pages.
- Planning our Fall 2016 Introductory Training Workshop.

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