Introductory Patient Training Workshop

www.USAPatientNetwork.org

Our October 2016 Introductory Patient Training Workshop was an exciting 2 days of motivation, collaboration, and learning. The goal of the workshop was to increase patient partners' understanding of research that is designed to determine the safety and effectiveness of medical products, so that participants can be better informed, more confident, and more likely to share patients' perspectives with researchers at federal agencies and medical centers.

Thirty patient partners participated from 19 states and Washington, D.C. The Introductory Patient Training Workshop was led by staff of the National Center for Health Research (NCHR). Guest speakers included keynote speaker Kim Witczak, who talked about her journey to patient advocacy; Dr. Susan Wood, the former Associate Commissioner for Women's Health at FDA and current Professor at George Washington University; and FDA's Salina Prasad and Andrea Furia-Helms, who led a Q & A session on behalf of the FDA patient representative program.

Kim Witczak, founder of Woody Matters and patient advocate, gave a motivational talk on how she became a patient advocate.

Patient partners learned about the different types of clinical trials, the FDA approval process, and the importance of including women, men, people of color, and people under and over 65 in clinical trials. They also learned how to scrutinize information provided on TV drug commercials. Short presentations were combined with Q & A's and small group sessions to discuss examples of the concepts presented.

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 Advisory Committee members and public comment speakers, in favor of or opposed to Belsomra. This interactive learning experience gave participants an opportunity to test their skills and gain confidence about expressing their views at research-oriented meetings. This gave participants a better understanding of federal Advisory Committee meetings.

This is the third of four Introductory Patient Training Workshops hosted by the National Center for Health Research. A fourth Introductory Workshop will be held in Spring 2017. For more information, contact info@USAPatientNetwork.org.

Patient advocates Tess Schulman, Raylene Hollrah, Amanda Dykeman, Angela Lynch, Chandra DeAlessandro, and Jamee Cook (from left to right)

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. Great news! Results show that participants knew significantly more after attending the Workshop.

Since some of the participants were experienced patient advocates, they already had some knowledge of the material. Before the workshop, more than 50% of participants answered 8 of the 13 questions correctly. After the workshop, participants scored nearly 80% or above on more than half of the questions, including 100% accuracy on three of the questions: defining a double blind clinical trial, why subgroup analysis is important, and what statistical significance means. Participants' scores improved on every question, although not all differences were statistically significant. The results are shown below.

Question	Friday Answers (% Correct)	Saturday Answers (% Correct)
Q#1 Criteria for FDA drug approval	63%	86%
Q#2 Drug vs. device standards	70%	96%
Q#3 Matching clinical trial types	Uncontrolled 47%	64%
	Randomized & Double Blind 77%	100%
	Random/Controlled 60%	79%
Q#4 Define biomarkers or surrogate endpoints	63%	71%
Q#5 Advantage of studying surrogate endpoints	59%	79%
Q#6 Importance of subgroup analysis	93%	100%
Q#7 Differences between pre- and post-market studies	A. 27%	61%
	B. 13%	43%
	C. 27%	68%
	D. 43%	68%
Q#8 Meaning of statistical significance	90%	100%

We also included open-ended questions and asked participants to share their views on important issues covered in the workshop. After the workshop, participants provided more informed opinions regarding direct-to-consumer advertising and the FDA approval process.

Participants' Evaluation of Workshop

Participants were 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 as a whole was rated as a 5.0 out of 5.0 and the speakers as a whole were rated 4.9 out of 5! Participants reported that they learned very helpful information about FDA standards and clinical trials and how they inform decision making at the FDA. Participants thoroughly enjoyed the small group activities and appreciated the high level of interaction and lively discussion. They also enjoyed hearing personal stories from other patient advocates and said their stories were inspiring, motivating and encouraging. Participants loved the "Mock FDA Advisory Committee Meeting" and reported that it could be a stand-alone training.

Overall, participants said they were thankful for the opportunity to attend the workshop and look forward to working with the USA Patient Network and NCHR.

	Workshop Session	**Average** (Range)
Friday October 14, 2016	1. Advocacy Matters, by Kim Witczak	**4.8** (4-5)
	2. FDA Standards by NCHR's Diana Zuckerman.	**4.9** (4-5)
	3. Intro to Clinical Trials by NCHR's Miara Jeffress, Training and small group discussion	**4.7** (4-5)
	4. How You Can Get Your Voice Heard at the FDA by Susan Wood, Presentation	**4.7** (3-5)
	5. How Advocates Have Reached out to the FDA and to Researchers by Katherine Leon, Angela Lynch and Rachel Brummert	**4.9** (3-5)
	6. FDA opportunities for Patient engagement Q&A by Andrea C. Furia-Helms and Salina Prasad, both of the FDA.	**4.9** (3-5)
Saturday October 15, 2016	1. The Importance of Sex, Race/ Ethnicity and Age when Treatments are Studied by NCHR's Stephanie Fox-Rawlings, Training and small group discussion	**4.9** (4-5)
	2. Opportunities for Patient Engagement at the FDA and NIH by NCHR's Paul Brown	**4.9** (4-5)
	3. Mock FDA Advisory Committee Meeting	**4.9** (3-5)
	4. Vision for the USA Patient Network	**4.7** (3-5)
Overall	Speakers/Moderators as a whole?	**4.9** (4-5)
	Workshop as a whole?	**5.0** (4-5)

What participants said we did well:

- Provided detailed explanations on the FDA approval process for new drugs and devices.
- Provided helpful information on future patient engagement opportunities.
- 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:

"Words cannot express how helpful these two days were, the NCHR and fellow attendees, excellent."

"I am very impressed with the training – I plan to testify at the public hearings in November for off-label use of drugs and these workshops have been very helpful."

"Appreciate the time and effort to put this together-one voice is important but a set of collaborative voices is powerful, I think this was a wonderful opportunity-2 days jam packed with helpful information."

What we can improve next time:

- Clarify the goal of the USA Patient Network
- Explain the roles/expectations of USA Patient Network members
- Include a session on social media
- 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 the new patient partners 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 USA Patient Network website under the tools section (www.USAPatientNetwork.org). Webinars are posted on the USA Patient Network website, based on presentations and Q & A sessions, as well as the Mock FDA meeting, several in the Tools section, and others in the Members only section. Several members testified at the FDA Unapproved Uses of Approved Medical Products Advisory Committee meeting on November 9-10, 2016. Participant Jonathan Furman spoke at the FDA meeting on behalf of the USA Patient Network about the need for informed consent regarding the risks of off-label prescriptions.

Participants are welcome to reach out to NCHR with any questions, comments, or suggestions about the USA Patient Network by contacting Miara Jeffress (mj@center4research.org). Policy questions should be sent to Jack Mitchell at jm@center4research.org.