THE PATIENT'S VOICE CAN'T BE IGNORED IN CLINICAL RESEARCH

A series of live panels from the WCG Patient Advocacy Forum in Washington D.C. in October 2019

Introduction

Effective patient input across the drug-development continuum requires sites and sponsors to listen to patients, truly hear what they have to say, and incorporate their insights into clinical trial design and execution. Although the situation is improving, the patient voice is not yet widely incorporated into the clinical trial process.

So what can sponsors, sites, advocates, patients and caregivers do? The inaugural WCG Patient Forum, "The Patient's Voice Can't Be Ignored in Clinical Research," took on this question. Panels touched on an array of topics, including diversity, compensation, informed consent and returning study results to research participants. One of the most important recurring themes was the individual as a fully human participant, not a passive vessel, and most decidedly not merely a "subject."

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Not a Passive Vessel

Journalist and author Mary Elizabeth Williams focused on that theme in her keynote, “Patients’ Experiences: We’re Missing a Critical Part of the Development Team.”

Williams is the author of A Series of Catastrophes & Miracles, her account of being one of the first patients in the world in an innovative immunotherapy clinical trial. She got things off to a rousing start, telling the industry leaders in the audience that, as a patient, she realized she was merely “a passive vessel for brand new drugs--who has no agency, who has no voice, who is there to simply take orders.”

That’s not necessarily how sponsors and sites think about patients, she acknowledged. “But the fact is, this is the language most of the healthcare industry writes and speaks in; it’s the language the doctor uses to tell you what to do.”

That’s one reason why “informed consent” seems ludicrous. “It is a complete misnomer because most of us, when we are in the position of being a patient, do not feel like we are informed. We do not feel like we are truly consenting. We consent in the same way that we consent to the updated terms of service on our app, which is click a box and hope it’s okay.”

In 2010, she was diagnosed with melanoma and underwent surgery. Then, a year later, she was re-diagnosed as stage four. “The cancer was in my

lungs and it was in my soft tissue. And moving very quickly as a metastatic melanoma is wont to do." Her oncologist recommended immunotherapy. "This is 2011. I didn't really know what the word 'immunotherapy' meant."

She learned. It worked. "I have been allegedly cancer free ever since."

She emphasized that her experience is far from universal. "I'm just here speaking for myself as a person who is white, who is educated, who lives in Manhattan and has easy access to one of the best cancer facilities in the world. I had a flexible work schedule. I had infinite support around me. Most people don't have any of that." She also had great health insurance and, as a journalist, was used to asking questions and pressing for answers. "Very, very few of us have the kinds of options that many of the patients here in this room have had. But every single one of us has the same rights. Every single one of us is entitled to the kind of care that I received. Very, very few of us receive it."

Even then, she was scared. "So I had all of that. I had all of that, and it was still the scariest, most nail-biting, traumatic thing in the world."

She made the case for change: Fewer than 10% of qualified patients enroll in clinical trials. Of them, fewer than 5% are African American. "That doesn't change unless we change every single aspect of the development process," she argued. "Because by the time I am handed a 27-page document that looks like gibberish to me... it's too late to have this kind of collaborative,

respectful, egalitarian relationship that you need to have if you're going to participate in a clinical trial."

After all, she added, if you have been dehumanized every single step of the way, how do you come into that room with any agency?

"I love where we are right now in this process, that we can learn so much about who might be good for a trial, and what kind of drugs might be good for them," she said. "But I also wish we'd just use some damn common sense and thought about the barriers to access." How hard is it for somebody to get to the clinic? How hard is it for the doctors in that clinic to run a trial, to run a protocol? What kind of support are they getting?

It's time to make that process collaboration and make sure the patient understands, "I am not just a passive vessel. I am a historian. I have something to offer. I'm here because I can tell you something that can help other people."

When patients understand that, everything changes. "All we ever want to do at any point in our lives is feel like we have a choice." The fact that patients don't understand shouldn't be an excuse not to bring them in. "We don't understand, but that's why you need us. If you can't explain it to us, how are you going to treat us?"

Patients must be able to understand--how else can they give informed consent?

Panel 1: Diversity, Inclusion & Meaningful Participation in Clinical Trials

MODERATOR

Lori Abrams

Senior Director
Patient Advocacy
WCG

PARTICIPANTS

Jonca Bull

MD, Former Assistant Commissioner, FDA; history of advocacy and inclusion in clinical trials since late 1990s

Kimberly Richardson

Six year survivor of Ovarian Cancer; Research Advocate. Working with Cancer Survivors in the University of Illinois Cancer Center

Dorelia Rivera

Patient Advocate; Parent of a child with Ultra Rare Disease - NOMID (neonatal onset multisystem inflammatory disease); been in trials for 15 years

The persistent lack of diversity in clinical trials means many therapies are never tested on the very patients for whom they are intended. What can we do to make sure that study populations reflect patient populations, and that data is being generated that will be as generalizable as possible? Taking on this topic were panelists Dorelia Rivera, patient advocate and mother of a daughter with an ultra-rare disease; Kimberly Richardson, patient advocate and six-year survivor of a rare ovarian cancer; and Jonca Bull. former assistant FDA commissioner. Lori Abrams, senior director of patient advocacy at WCG, moderated.

Typically when we talk about health disparities, we think about racial and ethnic minorities, but that's just part of the problem. Abrams noted that those who are obese, those 15 to 35 and 65+, and members of the LGBTQ community are also underrepresented. It's not a new problem, but the situation is not improving--despite FDA efforts to encourage more diverse trials.

Precision Medicine Problems

Citing a Genome Biology paper, Abrams shared some distressing numbers: As of 2018, approximately 78% of individuals included in genome-wide-associated studies were of European descent. African Americans and Hispanics were 2% and 1%, respectively.

Abrams then asked the panel: How do we, the research community, begin to break down those barriers?

It starts with providing information. "I can speak for the community I love, the Hispanic community. It's a very word-of-mouth type community," Rivera said. The stories people hear about genetic testing are off-putting, even frightening. "So

I think the first part would be access to information about genetic testing." The second is access to the testing itself.

It's a matter of taking half a step back to explain what a clinical trial is and what it does. "So I think getting to the why of a clinical trial is just as important as the 'What is it?'"

It comes down to trust.

The Shadow of Tuskegee

Many potential trial participants fear being a guinea pig for an unproven therapy. "I have participated in panels where issues around Tuskegee come up. And you have to face that head on," Bull recounted.

But she pointed out that another legacy of Tuskegee is the protections for patients that we have in place now: IRBs and informed consent did not exist before the Tuskegee Syphilis Study. But although protections exist many potential participants either don't know that--or don't believe it.

Educating--and reassuring--patients about the levels of oversight is essential. That requires cultivating trust. "Who are the trust bearers?" Abrams asked. Where can the conversations begin?

They begin where the people are. That can be social media, and they can begin in the local community. Rivera points to primary care physicians and faith-based communities as trust bearers.

Gaining that trust remains a challenge for an array of reasons. Richardson brought

up the fact people will do 23 and Me and think nothing of it. But when she mentions genetic testing in the context of clinical trials, the conversation turns to concerns about how the information will be used. “You’ve already spit in a tube, so what are you talking about?”

Overcoming that begins with explaining why. “Why are we asking for this information? What is it going to do for you today? What could it do for your family in the future?”

The challenge, the panel agreed, is this: How do we, at a community level, drive a more credible approach to genetic testing and encourage folks not to see it as a risky proposition, but as a way to drive better clinical outcomes for them and their families?

Genetic testing is tricky and complicated. But diversity in general shouldn’t be.

Diversity Isn’t Rocket Science

“We live in an age where we know where the patients are. You can look at CDC data. You can look at a heat map of where the patients with, for example, heart disease, are,” Bull said. “This is not rocket science.” We know where the heat is for whatever these diseases are. The question is, “Is that where we are gathering the data?”

Richardson related being at a conference that featured a panel on diversity. Every panel member was male. Another featured a panel of minority physicians in the hopes they’d be more relatable. They were not; they spoke the language of doctors, not patients. “I think I was the only person in the room that actually understood what they were saying because I’m a research advocate.”

What could they have done better? “I think it’s common sense. If you think it’s so

important for me to participate in clinical trials, then tell me like you would tell your grandmother," Richardson advised. "When we talk about clinical trials and we talk about safety and efficacy of drugs and a person's participation in that, we have to use examples that make sense to them."

Diversity doesn't begin with recruitment and end with enrollment. It must be integrated throughout the drug-development process.

Click here to read the full transcript of the discussion.

Panel 2: Compensation for Research Participation: Should We Worry About Too Little Rather Than Too Much?

MODERATOR

David Borasky

VP of IRB Compliance
WCG

PARTICIPANTS

Elizabeth M. Oehrlein

Senior Director
National Health Council

Jeanne Regnante

SVP, Community Education and Chair
Diverse Cancer Communities

Leslie Hanrnhan

SVP, Lupus Foundation of America

Historically, IRBs have been reluctant to support compensation for clinical trial participants. But attitudes around compensation have changed, partly due to the urging of patient advocates, partly because regulators increasingly recognize the role of compensation in research studies and, perhaps most important, because patients are recognized as team members rather than as subjects. This panel featured Elisabeth M. Oehrlein, senior director, National Health Council; Jeanne Regnante, SVP, Community Education and Chair, Diverse Cancer Communities Working Group, National Minority Quality Forum; and Leslie Hanrahan, SVP, Lupus Foundation of America. David Borasky, WCG's VP of IRB compliance, moderated.

Lay of the Land

Regnante shared some of the research from the Diverse Cancer Communities Working Group. Among the most relevant findings: Lower-income patients are less likely to be asked to be in clinical trials, suggesting that insurance status or a lack of understanding about who is going to pay for the treatment plays a role.

Lower-income patients are most likely to be concerned about costs of being in a trial, particularly older women and families with young children.

The Working Group also sought out success stories, interviewing 14 leaders in eight cancer centers across the country about successfully improving racial and ethnic minority recruitment. What are they doing? One finding speaks directly to the financial aspect: Successful center leaders ask everybody who is eligible for a clinical trial to come in. If someone doesn't have insurance, the center will get the insurance. They make sure the sponsors compensate patients for logistical support--and offer that support to anybody coming into the trial.

Too Much Certainty

The Working Group also surveyed its members and other industry leaders about reimbursement and compensation. Many responses came back with “it depends” and “it’s not standardized.” There was also little consistency in how terms such as compensation, logistical support, standard-of-care costs and patient assistance were used, Regnante reported. “It’s clear they believe out-of-pocket costs should not be a barrier to participation,” but no company surveyed had a standard model or calculator they applied to trials to figure out how to pay.

No one seems to have figured out what’s fair, Hanrahan said. “I think all of us are still wrestling with what the value is and what’s the right compensation. We want to do all we can, that’s why we’re there. We say ‘yes’ even when we really don’t have the right resources to do it, because that’s who we are, why we’re there. But it’s a very, very difficult topic.”

To address that challenge, the National Health Council is developing a fair market value calculator to figure out how to compensate patients and patient organizations who are participating in guiding drug development, Oehrlein reported. Neither the research community nor the patient community really knows what appropriate compensation rates are.

Caregivers and Compensation

Often, patients--especially the elderly and children--cannot participate in a trial without the caregiver. “We should think about compensation in the context of caregiving,” Regnante said.

Ellen Wagner--an audience member and part of the Demanding Patient-Friendly

Studies panel--emphasized the burden on parents when payment is made after the fact. “Reimbursement should be upfront but often isn’t,” she continued. “You’re expecting people to put it on their credit card--the cost for this travel. Sometimes that’s not a possibility. That limits the pool of people who are interested in the trial.”

Ask the Patients

Regnante pointed out that pharmaceutical companies are already getting input from patients on study feasibility and study design. “As part of that engagement with patients, ask them about what the compensation model should be. Get that input into the consent as part of that process.” Hanrahan agreed, noting that patients and caregivers can provide unique insights. “I don’t think we’ve asked caregivers enough, to be honest. I think it’s an untapped community we need to do more with, to understand better, in general.”

By convening focus groups of patients at the front end and asking, “Would this be a deterrent to actually participating?,” sponsors have been able to redesign clinical trials and avoid amendments, Hanrahan says.

Consider unintended consequences: Regnante pointed out that in 48 states, Medicaid does not reimburse the standard-of-care costs when a patient is in a clinical trial. Another issue is the potential taxability of reimbursement; that could be a factor in patients deciding not to participate. Oehrlein raised a related point: If you’re receiving compensation--even a small amount--you may potentially no longer qualify for Medicaid or some other benefits.

So, who should pay? If the pharmaceutical industry pays the investigators a certain amount of money it should fall upon the investigators to pay the

patients, panelists agreed--with provisions. Hanrahan again stressed the need for standardization across sites, across studies, about how the money is to be used. “I’ve been in three different studies and three different situations in terms of reimbursement. In one, I knew they used the money a different way. So that’s alarming.”

Sponsors should be clear in their expectation that participants in their trials are going to be fairly compensated or reimbursed, Borasky said.

Sites need more than direction, Regnante said. They need the resources. “Just because we asked the site to do it and provided a budget doesn’t mean that happens. I mean you have to make sure they have the ability and the headcount to do that. And I’m not really too sure they do.”

Participants in clinical research want something more than money for their efforts. They want to see the results of their trials.

Click here to read the full transcript of the discussion.

Panel 3: Improving the Informed Consent Process: How Do We Make Real Changes?

MODERATOR

Lindsay McNair

Chief Medical Officer
WCG

PARTICIPANTS

Mary Elizabeth Williams

Journalist and Author

Kristina Wolfe

Eversana, Our Odyssey PAG, and Patient Advocate

Alyssa Lanzi

Speech-Language Pathologist and Clinical Researcher

As protocols grow more complex, how do we ensure truly informed consent? How can the patient voice be incorporated to improve the informed consent process? In this panel, patient advocate Kristina Wolfe, who's living with diabetes, and Alyssa Lanzi, a speech-language pathologist and clinical researcher, joined Williams. Lindsay McNair, chief medical officer of WCG, moderated.

Paperwork Trumps Patient-Centricity

Williams recalled being a patient in the first cohort of a clinical trial for immunotherapy in 2012. She later realized she hadn't understood the consent process at all. "When I read my informed consent papers again, I realized how really confusing and obtuse they were. I hadn't in the moment, because I was traumatized and scared and sick."

Informed consent is not simply the informed consent document; it's a process and a conversation that goes on throughout the duration of the study.

Sites and sponsors often don't see it that way, though. "There's so much focus on the informed consent paperwork and what that says, and whether you've run it through Flesch-Kincaid software in Word," McNair said. "It says nothing about understandability of documents."

To aid understanding, Lanzi and her teams include pictures in consent forms to describe the key components. "We also embed true-or-false comprehension check questions, so even if they don't ask questions I can gauge whether they're understanding everything that's being asked of them and then enhance my conversation with them as well."

It's Personal

Participants in trials want to be treated as human beings, not subjects. "Subject," says McNair, is neither friendly nor welcoming. But because it's used in the regulations that govern researchers, it gets carried over into patient-facing materials and--worse--into conversations.

Lanzi works to make her students and research assistants recognize the importance of communication and the importance of that personal interaction from the outset. "Are they going to be comfortable enough with you in the session to ask you questions if they're unaware of the information in the informed consent?" Each encounter matters. "Any encounters I had in the medical process with people who didn't see me as a human being, informed my decision," Williams said.

Caregivers Have a Role

Lanzi often investigates treatment approaches for individuals with dementia or mild cognitive impairment. She understands the importance of including the caregiver. "I think a lot of people may not know they have the option to bring somebody with them. So having that conversation up front with them, telling them that other people have found it beneficial when they bring someone, is really important. During these conversations, think of the caregiver both as an extension of the patient, and as having their own identity."

The conversation with the caregiver may be different from the one with the patient, but both conversations must happen, Williams said. "And there has to be respect for both of them at every level, no matter what their ages, whether the patient is a two-year old or a 90-year old." Too often, the conversation is directed to the caregiver and the patient is ignored.

Customized Communications

Populations participating in or targeted for clinical research may make decisions very differently. “I think it also comes down to who is designing the trials, who is writing the language,” Williams said. “It also has a lot to do with being able to speak in the language of your actual patient population because you come from that population.” If everyone on your team is a 50-ish white man, how will they speak to a 25-year old Latina who wants to enroll in the trial?

Again, it comes down to “seeing us as full people, beyond just patients,” Wolfe said. That includes scheduling. She had to drop out of a trial during grad school. “There were too many things to consider in going to those visits to the site, and I wanted to continue, I wanted to continue to be involved, but the protocol didn’t allow me to do that.”

It begins a protocol design. “It’s important to include all stakeholders in the beginning when you’re developing your protocol, when you’re developing your documents,” Lanzi said. “We often try to have somebody with traumatic brain injury or somebody with Parkinson’s disease actually on our research committee that develops this study with us.”

Getting Buy-In from Site Team

Sponsors have a significant role here: Wolfe called on them to invest in developing relationships sites, “and then empower the sites to invest in the patients that you’re recruiting for your studies.”

Sometimes, McNair noted, investigators and research teams bristle at the notion of additional training, because they’ve been involved in informed consent for years.

"There's no doubt about that," Lanzi said. "I've now been at three different universities and every single time that's the first thing I do--talk to them about the procedures they've typically done and their protocols. Then I give them suggestions. As I'm giving them suggestions, their eyes widen. 'We've never done it that way before. I don't want to do it.'" But she wins them over.

Convincing the IRB

When sites try to use patient-centric language that doesn't make the patient feel like a passive vessel, they often get pushback from sponsors or IRBs. The challenge then becomes how to make a patient feel included and valued while following established guidelines.

"Always, always go to the IRB meeting where they are discussing your study. Build that relationship and provide the rationale," Lanzi counseled. Many times, the IRB simply doesn't know the rationale behind a modification to informed consent. Simply telling them, for instance, "Well, we do it this way because we had a patient with Parkinson's disease, and this helped them understand," is a hard argument to counter, she said.

Beyond the Squeak

Williams noted that the people participating in these panel discussions are the squeaky wheels--and that's important. "But we also have to be really working a little harder and pushing a little harder for the person who may just be blindly signing the consent form--who may just not be asking the questions. We can often figure it out for ourselves, but the ones who aren't complaining are the ones who probably need it the most."

Listening to only the squeakiest wheels also risks exacerbating one of the greatest problems in clinical research today: the lack of diversity.

Click here to read the full transcript of the discussion.

Panel 4: Demanding Patient-Friendly Studies – Effective Input Along the Drug Development Continuum

MODERATOR

Danya Kaye

Director of Business Development
R&D and Innovation, Inspire

PARTICIPANTS

Steven Taylor

President & CEO, Sjogren's Foundation

Ellen Wagner

Founding President & CEO of Parent Project Muscular Dystrophy

How do we make clinical studies more patient-centric? What does “patient-centric” even mean? Steven Taylor, president and CEO of the Sjogren’s Foundation, and Ellen Wagner of Parent Project Muscular Dystrophy (PPMD)--and the parent of a son with Duchenne Muscular Dystrophy (DMD)--offered insights into how patients and advocates can amplify their voices and provide meaningful input into clinical trials. Danya Kaye, director of business development, R&D and innovation at Inspire, moderated.

What is patient centricity? “Patient centricity” has been a buzz word in the industry for a while, but really there’s no consistency in terms of what it means in pharmaceutical and biotech organizations. So Kaye posed the question: What does it mean to be patient-centric? Is there a better term?

Both Wagner and Taylor agreed “patient-focused drug development” keeps the focus on the fact the drug is for the patient. Wagner added that, because DMD is primarily a pediatric disease, “patient” must include the caregiver. True patient-focused drug development involves making sure the key players--not just the patient advocacy staff--are in the room, listening to patients, Taylor added.

Listen to all the voices, not just the loudest: Patients and caregivers need to make their voices heard, all agreed. But it’s important not to listen only to the loudest voices. The squeaky wheels give input on a regular basis, Wagner said. “But how do you find the family in Tennessee with two Duchenne-disabled boys, and how do you make sure we’re getting their voices heard?”

It’s essential to ensure representation, Taylor agreed. “Sometimes the squeaky wheel talks a lot and the others just nod. Everyone thinks they’re in agreement, but

they're just nodding because they're shy. So you need to call them out and make sure they get a chance to speak as well. I think that's very important, so you don't get just one perspective and think it's everyone's."

Ongoing Participation Essential

Patient involvement should be long term. "It shouldn't be one and done," Taylor said. It begins before protocol design. If a clinical trial is already set in stone, the patients won't understand why they're being consulted.

Kaye noted that pharmaceutical companies often solicit patient feedback on protocol design because it checks a box. "They get patient and caregiver feedback, but they're actually not building in enough time to take action on that data. They're getting the feedback just to get the feedback."

Data, Data, Data

How, asked an audience member, do we convince sponsors to invest in true patient-centric efforts? Case studies are one important way, Kaye said. "Showing where the key points in patient burden are, the actions taken to reduce the patient burden and demonstrating tangible outcomes have been helpful."

Providing examples of companies that have successfully incorporated feedback and reduced their patient enrollment times and improved retention can make a difference. Failure can be instructive, too. Taylor pointed out previous failures can make the case for more patient involvement. "Unfortunately, it's not good for our patients when the trial doesn't happen, but it is a learning experience."

Kaye raised a related question: How can patients and caregivers give actionable

feedback to sponsors? Data, data and more data. When Wagner first became involved in DMD, there wasn't much data. "So one of the first things PPMD did was set up the first registry for Duchenne patients." Every time a trial opens, the PPMD registry scans for anyone who might be eligible for it and reaches out. That data, she says, is invaluable to sponsors.

Advocacy groups also have data and insights to help sponsors improve site selection, in terms of both geography and patient experience, Taylor and Wagner noted.

Patient stories: Quantitative data is essential, but nothing replaces patient and/or caregiver voice. "If you're going in as an individual patient you need to have data about your own disease--what it's like to live with it," Taylor said. That story needs to be relatable and concise. "What do you think they would want to hear if they're a researcher, a clinical investigator, what do you think is going to help them do their job? That's what they need to hear from you."

Providing and Collecting Information

Both organizations use social media to collect feedback from the community and to disseminate information about trials and about the disease itself. Annual and regional conferences provide another way for the groups to gather patient insights and share information and guidance. Regular email pushes, webinars and blogs keep patients and caregivers current.

Current and actively enrolling trials are posted and regularly updated, and the organizations reach out to potential candidates. That's also a good way to provide practical support. For instance, PPMD provides genetic testing for those who don't have insurance that covers it. It also closely monitors social media closely and

alerts sponsors to potential problems with sites, patient education, etc.

Engaging Caregivers

"I'm speaking from a pediatric perspective as the parent of a child in a trial," Wagner said. "I think that when the sponsors actually stop and listen to what the parents are saying about what they can expect from a child, the trial design becomes much clearer and much cleaner."

Caregivers can provide insights the patient can't. Taylor pointed to his mother as an example. "On weekends sometimes the joint pain is so bad that she can't really get out of bed, but she won't tell that story. The caregiver can tell the full story."

As patients and caregivers become part of the drug-development team, sponsors and sites must consider issues of compensation and reimbursement.

Click here to read the full transcript of the discussion.

Panel 5: It's About Time – Let's Return Study Results to Participants

MODERATOR

Behtash Bahador

Associate Director of CISCRP
(Center for Information & Study on Clinical Research Participation - ciscrp.org)

PARTICIPANTS

Seth Rotberg

Currently living with Huntington's Disease; founder of Our Odyssey; board of trustees, Huntington's Disease Youth Organization

Amy Joosten-Butler

Living with Colon Cancer

Rene Broach

Living with colorectal cancer

When people participate in clinical trials, they want to see overall results as well as individual ones. But most rarely do. How can we make this an expectation for study conduct? A three-person panel, moderated by Behtash Bahador, associate director of CISCRP, took on this topic. It featured Seth Rotberg, who has tested positive for Huntington's disease, Rene Roach, who lives with stage IV colorectal cancer and Amy Joosten-Butler, living with Stage IV colon cancer

A Flat Refusal

Given that there's no requirement to share trial results, it's little surprise that the answer to "If you participated in research before, have you received the results?" was a resounding "no."

Joosten-Butler is starting her sixth trial and has yet to receive results. When she asks at the site, the answer is "Oh, you don't get those, no, no." It is, she says, very frustrating. "We are not guinea pigs. We are human beings. We are patients. And we are putting off other treatments for the trial," she said. Roach, too, noted that receiving the results would help assure patients they were not guinea pigs.

Rotberg comes from a family with Huntington's disease but remains asymptomatic; he can participate only in observational trials and even then, he doesn't get to see the results. He calls on sponsors to share results with the participants before presenting them at scientific meetings. "They're the ones who took the risk. They should be the first ones to know if it was successful or if it failed."

Positive Experience, Until…

An interesting aspect of this panel discussion is that, for the most part, panelists had positive experiences in their trials--until it came to getting results. "We're

missing this opportunity at the end of the trial to really reinforce that, to show that you did do something important," Bahador said.

Joosten-Butler said it's "disheartening" to finish your part of the trial and then hear nothing. "What if a few years down the road some sort of tremor shows up from patients that used a certain drug? How would I know this little shake I have in my hand is not Parkinson's, it's just a minor side effect that has come from an investigational drug I took?" It's important, said the panelists, to ensure patients know the results and understand what the results mean to their lives.

Accessing Results--If and How

Patients should, of course, be able to obtain their results, but the panelists agreed they should also be able to opt out. Ideally, they added, results should be sent to each participant's physician. "They don't necessarily have to tell you, but they can be thinking, 'Okay, this is what I should screen for or what I should look for down the road,'" Roach said. "I think that would be very valuable."

There was also consensus that secure patient portals provide an excellent way to deliver results--in language a lay person would understand--to participants. Because some results may need to be discussed in person, patients could also be asked to call or set an appointment.

This aspect is crucial. Rotberg shared that when he had genetic testing for Huntington's disease, he didn't have a genetic counselor. Having the resources to explain the implications of the findings can go a long way to helping patients determine their next steps.

If you get the results, what then? Had Joosten-Butler received her results, she would have shared them with her family. “I think my family raises their eyebrows at me frequently. ‘You’re doing this again? Shouldn’t you be on standard care?’” With results, she could counter with “Here, read this. This is what I helped.”

That’s a common response from the trial participants with whom Bahador has spoken. “If they get the results, they’re far more likely to have conversations with their family, with their community about their trial experience because they have something to show for it.”

Doing that can generate more interest in clinical trials, Joosten-Butler said. “We become stronger advocates. We will bring the patients to you.”

Making it so: The question remains how to make this happen. Joosten-Butler touched on a theme that came up in many of the panels: “It’s the squeaky wheel: Squeak, squeak, squeak, and just keep bugging them. Hopefully, they’ll start to listen.”

It won’t be easy, Bahador warned. “Putting this information into an easy-to-read summary and then thinking about how we are going to communicate this effectively with patients and participants, is far more complicated than it seems. That’s just another reason why you need to start doing it yesterday.”

Click here to read the full transcript of the discussion.

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