INCREASING PATIENT PARTICIPATION IN CLINICAL TRIALS

PANEL 5

Returning Study Results to Participants

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

Introduction

There are many reasons the rate of failure for clinical trials is currently at 90%. One of the biggest reasons is a delay in recruitment. Behtash Bahador, Associate Director of CISCRP, recently interviewed clinical trials patients Seth Rotberg, Rene Roach, and Amy Joosten-Butler to uncover possible reasons why this could be happening. Their panel discussion, transcribed on the following pages, shows how revealing results of trials to patients can result in increased patient involvement in clinical trials and increase clinical trial success rates.

These discussions have been significantly edited for clarity and length.

The Panel

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 Roach

Living with Colorectal cancer

The Forum

Behtash Bahador

So to open our discussion, can you each tell me if you participated in research before, and if you have received the results?

Rene Roach

I'm a Stage 4 colorectal cancer patient. I'm currently in a trial at Johns Hopkins, and I've had countless vials of blood taken, two biopsies... and I couldn't tell you what was learned from any of that. I've actually asked both the doctor and my clinical trial coordinator, "How are other patients doing?" The trial has been going on since 2016. I know there are some results out there. And usually the response I get is something like, "Well, we know that we're having some positive results, but we couldn't tell you any specifics." They said that once the results get reported, everyone gets assigned a number. But they couldn't tell me if the one set that's doing well has a mutation, or if they're like me, without a mutation. They really couldn't tell me anything, and I don't know if I'll ever learn what they learned from this trial. I hope I do.

Interestingly enough, I'm part of Colontown, which is a Facebook support group all around the world. We have our own trial's group in-house, and we sort of compose our own results from trials. I do learn from that community. But in our group there's only been a few people on this trial that I'm on, so the data's mixed. It would be kind of nice to know.

I also think that as someone who's conducting a trial, you want to make a difference in the world, right? I hope my kids don't have to deal with

"...you want to make a difference in the world, right? ...Knowing that you made a difference, good or bad - just that you learned something. I think that's important for us as trial participants."

—RENE ROACH

what I'm going through. Knowing that you made a difference, good or bad - just that you learned something. I think that's important for us as trial participants.

Amy Joosten-Butler

Today is my five-year cancer anniversary. I ound out I had stage our colorectal cancer five years ago today. I have completed five clinical trials, and I'm starting my sixth at the National Institutes of Health.

I have received no study results from any of the sponsors from any of the trials I've participated in. I have inquired a little bit with the site facilities, the treatment facilities, and they say, "Oh, you don't get those, no, no." I also have had a multitude of tubes of blood that were taken, and then I get my result. It's my CMP (comprehensive metabolic panel) and my little measly amount of lab results. And it's like, "Gosh, I know that was only two tubes of blood. What happened to those other tubes? Was anything weird found in my blood work? Was there anything that could be taken to my local oncologist for possible other treatment opportunities?" I had no idea what my blood was telling the researchers or what it was indicating about my disease.

I've had several biopsies taken and all I'm told is, "Yep, colon cancer in your lungs." Well, big surprise. I learn nothing about what is being done with those tissue samples. It is very frustrating for a patient to go into five clinical trials while knowing nothing about what's going on with those trials. I would love to see some updates. I would love to be able to go into some sort of patient portal and just find out where we are with

"I would love to be able to go into some sort of patient portal and just find out where we are with these trials. How did my participation make a difference?"

—AMY JOOSTEN-BUTLER

these trials. How did my participation make a difference? these trials. How did my participation make a difference?

Seth Rotberg

My story's a little different. I come from a family impacted by a rare neurological disease known as Huntington's Disease. It's like having ALS, Alzheimer's, Parkinson's all rolled into one condition. My mom battled it for 17 years before passing away in March of 2015. And then, at the age of 20, I decided to go through testing. I tested positive for it. I'm asymptomatic, which means I don't actually fall into the criteria or eligibility for a lot of these trials. Which for me it goes both ways. I'm lucky I don't have any symptoms, yeah, but my voice is not being heard. My voice is not being addressed. I think that's one of the biggest challenges: I can only participate in observational trials. And even when I do participate in them, I still don't get results.

I participated in one exercise study to see if it delays the symptoms and I reached out to them several times. They just stopped responding to my emails saying, "Oh, we don't have the results; we're trying to figure it out. We'll get back to you." And do I ever hear back from them? Nope.

It's very challenging because I wasn't even looking for individual results. I wanted to know the impact of the overall study. Did it find anything that might change my lifestyle, my quality of life? As in: "Okay, should I exercise more or make sure I'm eating healthier" and whatnot?

With this trial I'm involved in, they've been trying to recruit about 20

"I wasn't even looking for individual results. I wanted to know the impact of the overall study. Did it find anything that might change my lifestyle, my quality of life?"

—SETH ROTBERG

to 30 patients out of 30,000 in the U.S. They've been trying to recruit for two sites for about six months now. For me, I actually fall into the inclusion criteria, but I would have to take two weeks off of work. That's two weeks I could take vacation or go somewhere else. And then on top of that, it's also been a challenge for biopharma companies to try to understand the feedback from the patient's perspective and bring that insight into the clinical trial design earlier on. That's one of the bigger challenges from my perspective: living with Huntington's disease, and trying to understand how we can get our voices heard and ideas implemented earlier on in order to and get results to try and figure out what the next steps are in our own lives to manage our conditions.

Behtash Bahador

What would it have meant to you to get the results of the study - either during or at the conclusion of the trial?

Rene Roach

I think for me, it just would have meant feeling like I was more of a part of this whole process - that I wasn't a guinea pig. If I knew some of the things that they found out from my blood - just my personal results. I wouldn't stop the trial. I love this trial. It's been great for me, but there will probably come a time where it will stop working. It makes me wonder what to do after that.

And then I think, knowing that the trial's overall results and how it's going, just knowing that I personally made a difference... Gosh, that would be amazing, but unfortunately, I don't get that opportunity.

"Just to know that I personally made a difference... Gosh, that would be amazing, but unfortunately, I don't get that opportunity."

—RENE ROACH

Amy Joosten-Butler

I think it comes down to the word "participation." If biopharmas want us to participate in a trial, ideally, then that would include back and forth communication. We are not guinea pigs. We are human beings. We are patients. And we are putting other treatments on hold to try to make things better for us, and if not for us, than for other patients. I think it would offer a sense of completion if we were able to get those study results.

Seth Rotberg

It's about not just using the phrase, "patient inclusion," at a moment in time, but really implementing that throughout the whole clinical trial process. The term "patient inclusion" also includes providing the patient with their results. It also means a level of patient education and understanding. For example, what does it mean if the trial doesn't go from phase one to phase two. It fails? What can we learn as individuals because of that? Then share that with our friends and family, share that with other people who may have not qualified so we can continue to accelerate medical research and understand what the faults were. We can learn from that as a community, as a group. It's not just separating the patients from the nonprofits, from the pharma companies, from the CRO, but it's how we really bring all those pieces of the puzzle together to really accelerate research and really understand what the results mean to us as individuals.

Behtash Bahador

Can you tell us what your trial experience has been like? How did not getting your results change your perception of the trial?

"...we are putting other treatments on hold to try to make things better for us, and if not for us, for other patients. I think it would offer a sense of completion if we were able to get those study results."

—SETH ROTBERG

Rene Roach

I'm currently still on the trial, so I still hold out hope I'll find out something. Maybe having that knowledge will change things about how I cope with my disease.

Amy Joosten-Butler

Clearly, I have a whole lot of hope for clinical trials - since I've been doing so many of them. I want to live, and I want to help the pharmaceutical companies help me live. I'm a big fan.

That being said, it is disheartening to have your part in the trial be finished and then feel like it's just dropped off, without being able to learn what you did to help this company. What did I do to help push this drug through? Or did we find that the drug didn't work? I'd like to know that too.

What about late-stage side effects? For me, it's having so many different drugs in different trials. 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, and it's a simple little side effect that has come from a drug I took. These are important things for me to know and be aware of, things I worry about every day. And I think, to some degree, it does taint the perception of clinical trials when you don't have that sense of communication or completion.

Seth Rotberg

Again, my experience is from an observational study perspective, but I'll

"How would I know this little shake I have in my hand is not Parkinson's, and it's a simple little side effect that has come from a drug I took..."

"...to some degree, it does taint the perception of clinical trials when you don't have that sense of communication."

—AMY JOOSTEN-BUTLER

give you one example this discussion made me think of. My mom was on an already FDA-approved drug, so while she never participated in a clinical trial, she was on the drug for her physical symptoms. One of the challenges was that the side effects increased her depression, which impacted her cognitive and psychiatric symptoms. It's how you look at the clinical trial holistically, even after its approval.

For me personally, if I participate in a clinical trial, what do I want help with the most? Far and above, it would the cognitive and psychiatric symptoms that a patient experiences. I would rather deal with the physical symptoms. That's just my opinion. But how do I get my voice and my thoughts into clinical trial design and early enough so pharmaceutical companies can look at measurable outcomes for the cognitive and psychiatric improvements?

Behtash Bahador

According to industry studies, patients are having good experiences in trials, generally speaking. And yet we're missing this opportunity at the end of the trial to really reinforce that, to show that you did something important.

Rene Roach

I want to bring up something related to me. But I have a close friend who was diagnosed with early-stage Alzheimer's. She's 50 years old, and she was on a clinical trial at NIH with a drug and they just dropped it. They just canceled it. She found out afterward she was getting the actual study drug, not placebo (it was a blinded study). And she felt like

"...we're missing this opportunity at the end of the trial to really reinforce that, to show that you did something important."

—BEHTASH BAHADOR

she was getting treatment benefit by being on the medication, but she has no idea why they stopped the trial. No one will tell her anything. That's another example of where just knowing, "Okay, we stopped this trial because people were dying or something else was happening." But to just drop it without any communication is terrible, I think.

Seth Rotberg

One other thing is making sure that if we do get the study results back, that we sit with someone to discuss and understand what the results mean. What does that next step mean? I learned in grad school what "statistically significant" means, what the "P value" means, but if I were to ask the larger Huntington's disease community, maybe not all of them know what that means and what the results entail. It's really making sure that you can break down the results, whether it's a visual or something else that makes sure patients understand. We need an answer to, "What do my results mean? What does the overall picture of the results mean for the next steps in my life?"

I think that's a big thing we sometimes don't address - understanding and educating the community on what the results entail.

Behtash Bahador

And that's such an important part of it, Seth. Like you said, what's the context? How does this change your patient's life right now? What should I do with these results? To that end, I would ask: had you received your results, what do you think you might've done with them besides just read them?

Amy Joosten-Butler

I think I would've shared those results with my family. I think my family raises their eyebrows at me frequently. "You're doing this again? Shouldn't you be on standard care?" Because I'm still not. I have an active disease. It's growing all the time. I think it would bring a sense of, "Here, read this. This is what I helped." That would be big for me because I do have a lot of people wondering, "Why are you doing this?"

Behtash Bahador

Yes. That's one of the things we've found in our communication with patients who were in trials. If they get the results, they're far more likely to have conversations with their family and with their community about their trial experience because they have something to show for it. I wonder too, is that feedback something that you share with your doctor?

Amy Joosten-Butler

Absolutely. Yeah.

Seth Rotberg

We know that 90% of trials fail. One of the biggest reasons is a delay in recruitment, and maybe it's empowering individuals to be ambassadors or educators to the community saying, "Hey, these are my results. Here's my experience. Let me know if you have any questions when you decide to participate. Or, if you're interested in participating, I can help you understand what it means to participate in a trial."

"If they get the results, they're far more likely to have conversations with their family and with their community about their trial experience because they have something to show for it."

—BEHTASH BAHADOR

Amy Joosten-Butler

Right. We become stronger advocates. We can bring the patients right to you.

Behtash Bahador

I wonder, I don't want you to rank what is most important as far as what type of results you get, but how important would it be to know which medications you took during the trial? How do you think that would change your perception of the trial, and what would you do next?

Amy Joosten-Butler

For me, knowledge is power. I want to understand the medications that I have taken and be able to follow down the line whether they are working for others. They might not have worked for me, but I sure hope they're working for somebody else. Being able to know I participated in a trial that is helping to find a cure makes me feel great. Even if I don't make it, then it's part of my legacy that I helped push that drug forward. And I think knowing that there are possibly going to be some side effects down the road, would enable me to be better prepared if I know what they might be.

Behtash Bahador

In terms of individual results: I've met some folks who, if there's an incidental finding, they don't want to know the result - unless it's critical to their livelihood at the moment. Maybe there was genetic testing and they found a marker for something else. Should folks be able to opt out of getting individual results? Should there be something that goes to

"Being able to know I participated in a trial that is helping to find a cure... Even if I don't make it, then it's part of my legacy that I helped push that drug forward."

—AMY JOOSTEN-BUTLER

the doctors so the doctor is the one that makes the call about whether it should be shared with the patient?

Rene Roach

I think both. I mean, I think patients should have the power to decide if they want their individual results or not. I would want to know. That's just me, but my husband would not want to know. And having your doctor aware of your preference...they don't necessarily have to tell you, but they can be thinking in their head, "Okay, this is what I should screen for or what I should look for down the road." I think that would be very valuable.

I just think patients need to have more power in this, more of a say.

Amy Joosten-Butler

If a patient doesn't want to know, they absolutely have the right to say, "I'd rather not know. I'd rather not know the nitty gritty." I'm not one of those people.

Seth Rotberg

I agree. With genetic testing for Huntington's disease, I didn't have a genetic counselor. I should have had a genetic counselor. I didn't have the resources. Just having those resources can make the biggest difference in making sure if they do find something, and if the patient wants to know, they know what those next steps entail instead of having to go to Google.

Behtash Bahador

I'm really glad you're talking about that because a lot of the things that we're talking about here today come from a public health, programming perspective, right? What we really need to take into account are all the different determining factors that go into an individual's decisions and their behaviors. And there are a lot of systems-level issues we need to address as well. You guys mentioned that you followed up with the sites. You asked, "Can I have the results?" And the response was…

Amy Joosten-Butler

"We don't have them."

Behtash Bahador

That's right. That's because the sites themselves don't necessarily have the results. And they're not allowed to disclose them to you unless they have the okay from the sponsor, who is the "holder" of the data. Current regulations don't require the release of results - especially plain-language results. The stated reason? They don't know that sponsors consistently and adequately prepared a plain-language summary that is always non-promotional and unbiased. At CISCRP, we vehemently disagree. There's absolutely a way to prepare it so it's non-biased and non-promotional, and that includes co-creation among the patients in that disease area, patient advocates, healthcare professionals, etc. But this is one of the system-level concerns. The sponsors themselves see that and they say, "Well, the FDA hasn't disallowed it, but at the same time they said, 'You better not be promotional with this. They might get dinged.'" Right? The EMA

[European Medicines Agency] is taking the right step, I think. They've taken the plunge, and let me tell you, a lot of sponsors are finding difficulties right now in preparing these plain-language summaries in a way that meets the needs of their patient populations, but they have to go through those growing pains. They really need to. Some sponsors are early-adopting them and some are not.

This leads me to the next question. When sponsors are designing these programs to share results to create these plain-language summaries of results, how should they do that? How should results be shared? It needs to be in plain language much like the conversation about informed consent, but I think there are a lot of other considerations as well. I'd love to hear from you guys. In your ideal world, had you actually received the results, what would that process have looked like?

Rene Roach

I think the concept of a patient portal makes the most sense because I know talking to my doctor at Hopkins, the big concern is the HIPAA laws, right? You have to protect patient privacy, and she's like, "Even when they take samples from me, it just gets a code." My name's not associated with it. But there should still be a way that I can track it. You can have a special password or code that only I would know. I could go in and type it in, and I could have access to these things. In this day-and-age there has to be a way to overcome this issue.

That's what I would like to see.

"a lot of sponsors are finding difficulties right now in preparing these plain-language summaries... but they have to go through those growing pains."

—BEHTASH BAHADOR

Amy Joosten-Butler

I think this is something the treatment facilities could open up - a position for someone to get these results, make them safe for us to see, and put them on our patient portals at our treatment facilities. I don't understand why there couldn't be someone mandated at the treatment facility to get these results from the sponsors. However, make the language understandable for a lay person. Then put them on a portal or at least give us a little message. "Check-in with us. We have information for you." I feel like the internet is used for everything else, including medical records. Why can't we use it to get these results?

Seth Rotberg

I agree, a patient portal makes the most sense. And then if there needs to be any follow-up, if there's any confusion on what a patient is reading or doesn't understand how to interpret the data, you're able to simply message back or say, "Hey, let's set up an appointment to meet in-person." That also takes away from those automated phone calls where you have to wait 20-30 minutes to talk to someone just to schedule an appointment. Then you go in and it's a long hassle. You may be able to look at the results, figure some of it out, and then ask any quick follow-up questions. If there's a way to do it securely with a password or just a way where we can make the process more manageable, then why not try it?

Behtash Bahador

I think the NIH thinks that clinicaltrials.gov is a great way to share results with participants in public. I mean it's very well-intentioned,

"I feel like the internet is used for everything else, including medical records. Why can't we use it to get these results?"

—AMY JOOSTEN-BUTLER

right? But the results you see there...first of all, it's not required for every study that all results are recorded. And second, it's tables and numbers and listings and no narrative. You need to have that narrative context.

We need to have the results on paper or on a portal. And then you also need someone to help you interpret them. The other thing I would submit here is that the plain-language results, they're not just for patients and their families and the public. I guarantee you some of these investigators and these nurse coordinators that had very little time in their day would love to have a very brief and easy-to-understand version of what was going on in this trial, considering they aren't getting these results either.

Rene Roach

And the site staff develops relationships with us. They want to be able to complete the process for us as well.

Behtash Bahador

Yeah. When we did some of our initial feasibility testing, we spoke with about 50 sites. There was one individual at one site who said, "I think this might be too burdensome." 49 out of the 50 people we interviewed said, "Please give us the results. We want to give them to the patients we're treating; they deserve to have them. We want to know what was learned. This is really important for us."

Some of these studies are long, right? You may leave the trial after six months. It's still going a year, a year and a half later. Providing a portal

"We want to give the study results to the patients we're treating; they deserve to have them. We want to know what was learned."

—BEHTASH BAHADOR

or a postcard that updates you on where the trial is and tells you where you can go and see results. “Hey, go to this portal. It’s easy, and we’ll have help for you to help interpret the results.” All of these things are critically important.

In your conversations with folks involved in conducting the study—whether it’s a site or someone else—are you asking, “Why don’t you have the results?”

Amy Joosten-Butler

When I started clinical trials, I asked that question to the site staff directly. I was told, “We don’t get those. We don’t get them. You’re here, and we’re here to work with the pharmaceutical companies. But in all honesty, this is for development of the drug, and we don’t get the results of that.”

Behtash Bahador

Right. And I think that’s part of that education piece and part of the empowerment piece. The self-efficacy piece is patients who are going into trials should know whether they can ask for the results. Have you guys had these experiences? These conversations?

Seth Rotberg

No, because I knew I was going to do the trial either way. The other thing about informed consent is that they try to sum it up within two minutes because they want to try to make you go as fast as possible. “Here’s 10 pages, I’m going to give you two minutes to read them.” I went through

“The other thing about informed consent is that they try to sum it up within two minutes because they want to try to make you go as fast as possible. Here’s 10 pages, I’m going to give you two minutes to read them.”

—SETH ROTBERG

it and understood the summary, but I did mention, "Oh, it'd be great to understand and learn about the results."

I think the other challenge is that it depends on who's running the trial. If it's through a University, it might be more challenging because we're looking at staffing resources. I also think that when it comes to a pharma company, maybe they don't understand that patients want results. Maybe they somehow don't have the resources to provide the results. If they don't, then let's figure out a way to get those resources so we can analyze it and maybe get a staff member who can work with the community and break it down.

Amy Joosten-Butler

I have to say, for informed consent, I had a very good experience where a nurse navigator literally went through every single page. You're talking about every single possibility for the 20 pages. Everybody was out of breath and it was very warm in the room by the time we were done, but I have had good experiences with informed consent. Even though they are daunting and they're long, nurse navigators make the difference in treatment facilities. Maybe they could do the same with providing study results to patients?

Behtash Bahador

So, how do we move the needle here? How do we help the audience know what the next steps are to make a difference, to make a change? As I said, there are companies out there that are sharing their results. And there are some who claim they're sharing individual results. I can't

confirm whether they are or not, but how do we really move the needle? As patients, and then as a community, what can we do to really make a difference there?

Amy Joosten-Butler

It's the squeaky wheel: Squeaky, squeaky, squeaky, and just keep bugging them. Hopefully, they'll start to listen eventually. Hopefully the treatment facilities will go to the sponsors and say, "Hey, we really need to work on this program." It's all about communication. If we can make this all cohesive, what a beautiful thing it would be. If we all had our part in developing a drug and everybody communicated about it, then it could be a beautiful process. That's my hope.

Rene Roach

I agree. I know in the colorectal community, we always talk about people waiting until it's too late to get into trials. When you first get diagnosed, you're like, "I don't know if a clinical trial is right for me." But if you made it so that being in the clinical trial from start to finish was such a positive experience...even if the drug didn't work, but just the fact that you have more and more people talking about development progress and talking about their experiences and everything is explained to you. What does it mean that I had 20% growth on my scans? Exactly what does that mean? And that's another point. I get my scan results, but the report only talks about two or three target lesions. Talk to me about the whole scan.

Seth Rotberg

I think also sharing it with the participants before you're sharing it at

"If we all had our part in developing a drug and everybody communicated about it, then it could be a beautiful process. That's my hope."

—AMY JOOSTEN-BUTLER

scientific meetings is important - trying to explain it and trying to break it down to patients first because they're the ones who took the risk. Patients should be the first ones to know if the therapy was successful or if it failed.

A lot of times results are only shared at these big scientific conferences if they are successful, but what happens if they fail? I know it's a very competitive market, but at the end of the day, if you're really patient-centered, you're going to make sure the patients are aware of it and that other companies trying to do similar work don't make the same mistakes and don't reinvent the wheel. It's a lot easier said than done, but that's my viewpoint: how do you go about it in that way? How do we navigate so that the results are being shared in an easy way to understand, what are those next steps, and how do we all work together and collaborate in that way?

Behtash Bahador

Now I know you guys have worked with patient advocacy organizations - and Seth, you founded one. From that perspective, how do you guys think you can leverage the new relationships you're building with pharma and others to encourage sharing results?

Seth Rotberg

This organization I co-founded (Our Odyssey) really supports this young adult patient population—those with or affected by a chronic condition—18 to 35, who tend to not be addressed. There's a lot of focus on children and older adults; young adults have a different set of needs.

"...if you're really patient-centered, you're going to make sure the patients are aware of it [trial failures] and that other companies trying to do similar work don't make the same mistakes."

—SETH ROTBERG

We hope to provide that sense of belonging and improve the quality of life through social support, but how do we get them more involved in clinical trial participation? How do we make them more aware and educated?

For another young adult nonprofit group for Huntington's disease, I posted a short Facebook survey asking how many of them are aware what gene therapy is, and 70% said they had no idea. But they also said they would be interested.

So we have to start educating them and, at the same time, try to figure out what their challenges and struggles are. How do you get patients' perspective, at a younger age, to really accelerate it and really diversify your input?

Behtash Bahador

And I think of asking as a patient advocacy group and the sponsors working with you, asking them, "do you share the results of your trials? Do you share the individual results? Do you share the aggregate results?" Sponsors themselves, without making any excuses, are facing a lot of competing priorities as well. In the European Union they have something called "policy 70", which is a transparency and disclosure requirement. It's a law that basically says you have to publish anything that has to do with the clinical trial, if there is a request to do that. The FDA had a pilot doing the same thing. If there's ever a request for information about a trial that you've done, you have to fulfill that request, and you have to do it immediately. Health Canada is also putting these things in place.

"Folks are not going to try to reinvent the wheel when that wheel is going to be broken anyway."

—BEHTASH BAHADOR

These are all important because, as you say, by sharing more broadly, you hope to avoid unnecessary research, right? Folks are not going to try to reinvent the wheel when that wheel is going to be broken anyway.

Audience member

We have people from different stakeholder groups here, and I believe there are a lot of ways to make change. But I think data and large groups work really well together. I think at least eight pharma companies right now on their websites are giving the results of their trials. You can go on today and see the latest results.

What I would recommend if you're with an advocacy group and there are four pharma companies who are looking at colon cancer, I would see what companies are also doing oncology work and are posting their results on their site. That's hot data. You take it with you when you need it because they're going to want to work with you; companies need you. You need to start figuring out how to leverage what you can offer them.

I would say, "This is what we want in return." Because there are a couple of things you're going to want in return when you work with pharma. I know. That's where I come from. But you need to start telling them what you need rather than having them tell you what they need and what they're going to give you.

Behtash Bahador

Absolutely. One site is trialsummaries.com and there are several different sponsors posting mainline summaries of results there. And

many of those are in an understandable format. So that's positive.

Seth Rotberg

In addition to asking the patients or the participants, "What are you interested in learning from the results?", take that step back and ask, "Are you interested in learning about everything related to the clinical trial, or are there specific areas you are interested in learning?" This could include asking about short-term and long-term positive and negative impacts. "If this trial moves forward, what does that mean for me? What does that entail? If it gets FDA-approved, am I still going to have access to it and to what extent and how long do I have access until maybe I have to pay more?"

So try to really dive deeper and simply ask the nonprofits or the influencers how we could work closer with you and can you help us develop—even a 5-10 question survey—to understand the community's needs and what we're looking for when it comes to those results.

Behtash Bahador

Yeah, and I think the survey is important, but that direct communication is going to be critical because you'll learn on both sides. The EU regulation includes 10 required elements and then the guidance document has 50 other points you have to put in. You end up with a summary that has a lot of information, but it may not answer your questions. For example, they're asking only for the primary outcome measure to be recorded. However, we know things like quality of life measures in oncology trials, long-term survival, progression-

"If this trial moves forward, what does that mean for me? What does that entail? If it gets FDA approved, am I going to still have access to it?"

—SETH ROTBERG

free survival, overall survival are important, but they are not primary endpoints.

I will say, this concept of returning study results to patients is not an easy one to tackle by any means. 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. But, with collaboration of all parties involved—and the patient voice at the center—we can work towards progress. And in this case, we'll take progress over perfection.

Key Learnings

Improve public confidence in clinical trials by following the lead of the EMA

Though the FDA opened up the possibility that studies would be required to provide a plain language summary of results in 2007, nothing has come of that. In contrast, the European Medicines Agency provides a summary of results to all study participants as well as the greater public.

Inspire participants to become research ambassadors by showing them their impact

The lack of transparency over study results may be a missed opportunity for future clinical research ambassadors. Patients may feel more passionate about becoming an ambassador if they could see the impact of their treatment and would be more likely to recommend clinical research to others if they could point to their results.

Combat skepticism in patient families by increasing transparency of study results

Sharing study results could play an essential role in family buy-in to clinical research. We see that friends and family can often be skeptical whenever when patients consider joining a trial--especially if the patient has previously participated in clinical research without being shown results. Returning study results could go a long way in legitimizing the perception of clinical research in the support systems of patients.

Key Learnings continued...

Empower physicians to improve screening for future trials

The impact of transparent study results could extend beyond individual patient participants. The physicians of study participants could greatly benefit from seeing study results by helping to better make informed decisions and refine what to look for when screening patients for future studies.

Increase future participation ending ensuring a positive ending

We see more and more than patients are classifying their clinical trial experiences as positive—until it comes to getting results. The disheartening feeling of not knowing the results of your clinical research experience can cast a negative light on an experience that was otherwise very positive up to that point. By releasing study results, patients may be more inclined to consider their experience a positive one and be more likely to participate in the future.

Visit the WCG Institute to read additional discussions from the Patient Advocacy Forum

GO TO THE INSTITUTE