

*ACTION IMPACT XXV - Patient Engagement in
Planning, Conduct & Implementation/Dissemination of CPR*

October 29, 2021

*A Matter of Record
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5	INITIATIVE ON METHODS, MEASUREMENT, AND PAIN
6	ASSESSMENT IN CLINICAL TRIALS
7	IMPACT XXV
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9	Patient Engagement in Planning,
10	Conduct and Implementation/Dissemination of
11	Clinical Pain Research
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14	Virtual Meeting
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16	Friday, October 29, 2021
17	11:00 a.m. to 2:30 p.m.
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1	P R O C E E D I N G S	
2	(11:00 a.m.)	
3	Welcome and Housekeeping – Dennis Turk	
4	DR. TURK: Welcome back to all of you who	
5	have made it through listening to two days of these	
6	presentations. I think they're exciting. I think	
7	there's a lot of agreement among the organizers, as	
8	well as the chatroom, as well as the feedback we've	
9	been getting about how important and valuable this	
10	meeting tends to be, or has been, and we hope will	
11	continue to be. And I want to express the	
12	appreciation that you're able to come back for	
13	these three days.	
14	I particularly want to thank the organizing	
15	committee, but particularly Chris Veasley and Bob	
16	Kerns for the tremendous work they did in	
17	identifying the topics, structuring the meeting,	
18	and identifying the presenters. I think that	
19	they've done a tremendous job, and we really owe	
20	them a lot of thanks for doing that.	
21	This is the third day. We'll be winding up	
22	today. An important aspect of today will be the	

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1 last part of this meeting, in which we will begin
2 trying to have an outline and discussion about the
3 content of what might go into a research
4 publication, or a publication, that will in fact
5 address the important issues we've talked about.
6 Simon will be running that session, and we'll be
7 counting on all of you to contribute to that.
8 One point I just want to make before I turn
9 this over to Bob Kerns was, yesterday, Isabel
10 Jordan made an interesting point in which she
11 reminded us that people with lived experiences are
12 different. They're not all the same, and therefore
13 we can't assume that one person or one individual,
14 or even a couple of individuals, will speak for the
15 entire group.
16 Well, the same could be said about research,
17 and John Farrar reminded us that there's a
18 difference in the kinds of research that we're
19 doing. There's clinical research as a general
20 area, but there are also clinical trials, and there
21 are different constraints on clinical trials that
22 may be somewhat different, and we'll be hearing

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1 about some of those today. But I think it's
2 important to keep in mind that how we can engage
3 people with a lived experience in certain types of
4 studies may be very different than how we involve
5 them in other kinds of studies.
6 So let me turn this over to Bob Kerns, and
7 thank you all for being here.
8 Sorry. I forgot my housekeeping slides.
9 Since we've been over these two times already, they
10 should be familiar to you. We have added and heard
11 what you asked about the chatroom, and we've
12 included and opened the chat room, so that
13 information is available. We are maintaining that
14 information and sharing it so everyone can see it.
15 We appreciate that comment, and if you're finding
16 it helpful, great. It will be open today the same
17 way it was yesterday.
18 The other points on this slide are exactly
19 the same that you saw, so I won't read them off to
20 you. Carlos, just show the next one; it's the same
21 thing. Notice the importance of Valorie Thompson's
22 email address if you need information about

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1 anything that we've talked about logistically. She
2 can be reached at vthompson@mac.com.
3 Now we'll go back to Bob Kerns.
4 DR. KERNs: Great.
5 Welcome back, everybody. Good morning. I'm
6 excited to start day 3. And on behalf of Chris
7 Veasley, myself, and the entire planning committee,
8 and of course, Dennis and Bob and the operations
9 team, we all really greatly appreciate everybody's
10 involvement over the first couple of days, and we
11 expect the same today.
12 I'll make a special request that when you do
13 choose to speak -- and we hope you will speak up,
14 chime in with questions/comments, clarifying
15 questions this morning, and then as we move into
16 discussion this afternoon -- if you would please
17 turn on your video so we can see you when you
18 speak, and remember to unmute yourself.
19 Then especially during the discussion this
20 afternoon, we'd really like to have more of the
21 feel of a whole group participatory discussion.
22 Maybe at the risk of some bandwidth loss, we'd like

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1 everybody to turn on your videos. We really
2 strongly encourage -- we've had great participation
3 the first couple days, so we're not concerned about
4 this, but I do want to encourage everybody to feel
5 empowered to share their perspectives, particularly
6 this afternoon as we're flushing out the guts of
7 the recommendations or content for the paper that
8 Simon will be preparing.
9 Our plan is to go through a few
10 presentations this morning -- you see them on the
11 agenda on the slide today -- and then starting at
12 around 12:45 through 2:30, or however long we
13 choose to, maybe less, we'll spend, really, an open
14 discussion that will be facilitated by Simon with
15 Chris and I helping out. And it's during that time
16 that we'll really be focused on trying to shape up
17 our summary and recommendations in preparation of
18 an impactful publication.
19 So with that, I'm going to introduce our
20 first speaker. This is Dr. David Leventhal. He's
21 going to be speaking on the How Tos: Special
22 Considerations for Industry Pain Trials.

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1 Mr. Leventhal is senior director of Clinical Trial
 2 Experience at Pfizer, Incorporated, based in New
 3 York.
 4 Please take it away, David.
 5 MR. LEVENTHAL: Thank you, everyone.
 6 Bob, can you hear me alright?
 7 DR. KERNS: Yes, we hear you fine. Thank
 8 you.
 9 Presentation – David Leventhal
 10 MR. LEVENTHAL: Okay. Terrific. Thank you.
 11 And thank you for the promotion. I always wanted
 12 to be a doctor, but I'm not.
 13 My background, I've been at Pfizer for
 14 26 years, and I've worked in the space around
 15 patient advocacy and engagement for a good chunk of
 16 that. I'd like to briskly go through this content
 17 and get to a conversation.
 18 I think the most important thing is the
 19 story that I'm telling here is one of where you
 20 have a lot of individual advocacy around wanting to
 21 bring the patient voice into clinical research, and
 22 then being able to prove that out with a coalition

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1 of the willing, and then you build it in an
 2 organization, and then you sort of disseminate it
 3 out to the rest of industry. And that's very much
 4 how this story is going to be told. So I'm telling
 5 you the end of the story first.
 6 With that, the importance of partnership, I
 7 think, when you're a sponsor of clinical research
 8 is that what's driving us is that we have more
 9 informed and active patients than ever before; the
 10 idea that patient advocates really view the world
 11 as there's nothing about us without us activism,
 12 and we agree.
 13 We've seen this developing over the years,
 14 and internally within our organizations, we have
 15 felt that bringing the patient voice in is really
 16 important because we've struggled in many cases
 17 where in the absence of that patient voice, our
 18 programs don't do as well as they could. They have
 19 to go back for protocol amendments and other
 20 things. So we've always been of a mind that this
 21 is something that we should do, but the industry
 22 has struggled how to operationalize all this.

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1 We have those more informed and active
 2 patients. We have a regulatory and payer landscape
 3 which is demanding it. Our regulators have
 4 established expectations. Our marketing approvals
 5 are often at risk if we don't integrate the patient
 6 voice. Patients are advising payers about which
 7 patient-reported outcomes are most important.
 8 Payer decisions are going to be at risk if we don't
 9 do this, so that is a key component of this
 10 importance of partnership.
 11 Then I think at the end, to systematically
 12 embed the patient voice into our product life cycle
 13 requires a real commitment to standing it up
 14 operationally, and the benefit is we satisfy the
 15 changing regulatory background requirements, but
 16 we're also helping ourselves.
 17 By doing that, as we as say, you speed up by
 18 slowing down. And by putting in that additional
 19 work before you've finalized your protocol, we're
 20 reducing our protocol amendments, we're improving
 21 our protocol feasibility, improving retention,
 22 enrollment, and adherence, and those types of

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1 things.
 2 What we needed to do, in 2015, we had to
 3 prove this out. Through the Clinical Trials
 4 Transformation Initiative -- which is an
 5 FDA-sponsored, not just cross-industry
 6 collaboration, but cross-sponsor collaboration
 7 anchored around Duke University -- we had published
 8 a paper around patient engagement practices and
 9 clinical research, and got feedback from patient
 10 groups, industry, and academia to understand what
 11 were the barriers, I think, to engaging with
 12 patients.
 13 One of the outputs of that was what we call
 14 our Chevron diagram, which really showed where the
 15 opportunities to engage with patients and patient
 16 advocacy groups existed. And it really wasn't just
 17 around our phase 1 through 3 studies. There were
 18 opportunities in discovery and in preclinical,
 19 around natural history of disease, developing
 20 eligibility criteria, endpoints in PROs, and of
 21 course in phase 1 through 3, working with patients
 22 and advocates around benefit-risk and protocol

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1 design. These were all pretty clear opportunities.
2 We also found that in regulatory review,
3 supporting sponsors around those regulatory
4 meetings and giving public testimony in support of
5 regulatory review was really important, and then in
6 a post-approval space in those phase 4 studies to
7 continue to collaborate.
8 So getting those insights across the
9 continuum was, really, one of the findings of this
10 paper. There were two follow-on papers, one around
11 building and expected net present value calculator,
12 as well as showing that the expected net present
13 value of a research asset benefitted dramatically
14 from getting input from patients and patient
15 advocates.
16 Now, the link to all this work, I would
17 recommend that everybody go and look at this
18 content because it drove the decisions that we made
19 at Pfizer around how we operationalize this
20 internally.
21 Our work, we started this work in 2017. We
22 had been getting patient insights into our clinical

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1 programs, but in a rather ad hoc way. And every
2 time that we wanted to do it, we had to essentially
3 start from scratch. A clinical team would decide
4 they wanted to get patient input, and we would have
5 to develop a whole new set of legal agreements on
6 how to do that. We didn't have fair market value
7 payments established and any of that in place; very
8 hard to do. It took us many months to be able to
9 engage with an individual patient or advocacy
10 group. So it wasn't scalable, clearly.
11 We set some goals for ourselves in a
12 program, Global Product Development. The first
13 thing we wanted to do is bring together all of the
14 existing resources, which included things like the
15 city paper and other things, and communicate that
16 to the organization.
17 We wanted to build out the capabilities and
18 the legal framework to make it easier to enable
19 engagement, which for us meant there's going to be
20 a single set of legal templates -- a consulting
21 agreement or a partnership agreement with an
22 advocacy group -- that gets used by the

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1 organization rather than having to build a new one
2 every time we wanted to do it. Now, that may seem
3 silly that we do that, but this should seem
4 familiar to any organization who tries to do this,
5 that the legal framework tends to be built from
6 scratch every time.
7 The other thing that we did is we wanted to
8 test all of these tools in several of our clinical
9 programs before we scaled it to the organization.
10 This was kind of like a plan, build, run framework
11 for us, where we piloted all of the work in two to
12 three clinical programs; measured the value and
13 impact on that study; identified any gaps, any
14 recommendations; and then do continuous improvement
15 to make it better.
16 The result for us is we get a big change
17 management around this in the organization; that
18 every clinical team knows how and when to engage
19 patients and patient advocates in development; that
20 our colleagues in global product development are
21 doing this consistently and it's codified in the
22 organization; that they know how to incorporate the

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1 feedback and to realize that value to be able to
2 make those protocol changes before the studies are
3 locked down, and get to that place where we have
4 fewer protocol amendments and more improvement in
5 our recruitment and retention, and were all the
6 things that we, I think, said that were going to be
7 a better experience for the participant and better
8 for us, I think, in having studies that meet their
9 endpoints with the least amount of friction.
10 What we then did as part of our
11 communication to the organization was we created a
12 patient centricity hub, a website for the
13 organization that gives everybody access to the
14 tools. So the other thing is there shouldn't be
15 gatekeepers around this; that we make all this
16 available; and that it enables the study teams to
17 go as a self-service model when it can go and get
18 the tools that they need.
19 We deployed these tools to study teams to
20 make these partnerships easy. But the other bit of
21 it is we got top-down support from our senior
22 leaders in the organization to ensure that if

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1 you're going to have your protocol approved by our
 2 senior leadership, you have to meet these criteria.
 3 These questions get asked of anyone who's coming to
 4 our protocol review committee. Have you discussed
 5 your protocol with patients and/or the
 6 representative; does the protocol have relevant
 7 patient-centered viewpoints; and how do the
 8 complexity and timing of the treatments or clinical
 9 assessments of the duration of participation affect
 10 the patient?
 11 If the study team does not have those ready
 12 answers to those questions and the data to support
 13 it, then there's still work for them to do. So
 14 we've made this a core part of our protocol review
 15 process.
 16 The next bit of this is we did it as Pfizer,
 17 but there's an industry problem around this. We're
 18 not the only company that had this challenge, so we
 19 were very willing to share, through our
 20 cross-industry partnership, TransCelerate -- for
 21 those of you who don't know, it is a cross-industry
 22 collaboration of 22 large pharma organizations

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1 looking to solve clinical development problems in a
 2 pre-competitive way.
 3 Our view is patient engagement and patient
 4 advocacy input. This is a pre-competitive
 5 activity, and we think that it is something that
 6 everyone should be doing. So we launched this
 7 patient experience workstream through
 8 TransCelerate.
 9 Again, there are links to all of this work
 10 on the following slide. We created a Patient
 11 Protocol Engagement Toolkit, which reflects a lot
 12 of the best practices that we incorporated at
 13 Pfizer. I think the benefits are all the same
 14 benefits, but I think they're scaled now, so across
 15 industry, you're now seeing a much greater focus on
 16 this.
 17 Because many large pharma companies are
 18 partnering with one another, if one company is not
 19 doing this and another company is, then you end up
 20 having some differences philosophically in how we
 21 should be offering our protocol.
 22 So there's a whole series of capabilities

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1 that were addressed in the TransCelerate work and,
 2 again, we created a user guide for sponsors of
 3 research and created a resource guide, including
 4 what we call the Patient Protocol Engagement
 5 Toolkit, which includes all sorts of templates and
 6 tools for anyone who wants to do this, who's the
 7 sponsor of research. All that can be found at
 8 transceleratebiopharmainc.com in the Patient
 9 Experience space.
 10 Then lastly, I wanted to just make mention
 11 that our commitment at Pfizer has never been
 12 stronger. The leadership of Global Product
 13 Development published an opinion piece in Nature
 14 Reviews Drug Discovery last year about how COVID-19
 15 has really forced changes in how we're Conducting
 16 research.
 17 We have an accelerated approach now to
 18 conducting research within Pfizer, depending on the
 19 type of clinical program, and we've made some
 20 public commitments around the changes in research
 21 that we think are necessary. We are committing
 22 that participants on our clinical trials reflect

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1 the racial demographics of the country's
 2 communities that we work in and that we're
 3 committing to expanding awareness and access of our
 4 clinical trials to improve the experience of our
 5 participants. We're committing to share our
 6 knowledge, including our data, more broadly with
 7 the research community and embracing the digital
 8 tools for speed and quality.
 9 None of these commitments I think are
 10 possible without input from individual patients or
 11 patient advocacy groups. Underlying all of these
 12 core commitments that we've made publicly is the
 13 idea of getting patient input into the work that we
 14 do.
 15 I wanted to keep us on time, so we're right
 16 at nearly 25 after the hour. I've gone through all
 17 of my content, so what I'd like to do is I want to
 18 say thank you to everyone. I know I went over that
 19 all very quickly, but I'd like to open this up to
 20 questions to talk about any of this and any of the
 21 content that's been created over the years. Thank
 22 you, everyone.

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1 Clarifying Q&A
2 DR. KERNS: Well, David, thank you, thank
3 you, thank you. This was great. I learned a lot,
4 personally. I thought I knew something about what
5 industry and Pfizer were doing, so this was
6 terrific.
7 I want to open it up for clarifying
8 questions or comments, and I see Rick Malamut's
9 hand up first.
10 DR. MALAMUT: Yes. Thanks a lot, Bob.
11 David, that's a fantastic talk. I work at
12 Collegium Pharma, and I've been dealing with this
13 challenge my whole industry career as to how to
14 incorporate patient views but also not insult them
15 by telling them, "No, no, no, no."
16 Just to echo a point made several times,
17 that industry sponsor trials, where the regulators
18 are often your customer, are very different than
19 academic studies, and even different than perhaps
20 post-approval studies, where I think patient input
21 is crucial and maybe a little easier to
22 incorporate.

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1 There a question in here somewhere; it's
2 coming. I actually have two. I'll look at some of
3 what you said, but I have two main questions. What
4 specific topics, what specific areas, did you
5 really focus in on when speaking with patients?
6 Then the second question is about outcomes.
7 As you gathered this data, how often did you make
8 meaningful changes in protocols and study
9 procedures, and then what were they?
10 MR. LEVENTHAL: Great question. So again,
11 we do this for every study now, where it's
12 interventional. So all of our interventional
13 studies, we get patient input into them.
14 I'll give a real-world example, and we've
15 been public about this for our JAK1 study for
16 atopic dermatitis. There were two studies. There
17 was one in adults and a pediatric study. We
18 engaged, through the National Eczema Association,
19 with both individual patients and caregivers. This
20 is a very simple example.
21 We had a washout period on the use of skin
22 emollients in preparation for participation in the

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1 clinical trial. And if you know anything about
2 atopic dermatitis, the itching can be quite
3 stressful and maddening in many cases. We had a
4 washout period in our study that was deemed to be
5 too long by the participants that we were speaking
6 to, and we went back to the clinical team, and we
7 went back to the IRB, and we were able to reduce
8 the washout period for the use of those emollients
9 to 48 hours from something that was over a week or
10 more.
11 It's a very small thing, but the parents
12 whose children may potentially participate in this
13 clinical trial said, "Given this washout period, I
14 wouldn't enroll my child in this clinical trial"
15 because of this one particular thing. And this is
16 just one of many things that we do.
17 The other thing that we do is we do clinical
18 trial simulation under certain circumstances, where
19 we'll actually bring in participants and take them
20 through the daily schedule of activities; not in a
21 real way, but if you have to do -- some of these
22 require a blood draw and a battery of tests over

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1 the course of 6 hours, and in many cases, a
2 participant will say, "Well, I don't think I can do
3 that" and "You didn't really feed me very well at
4 lunch, and maybe I needed something else to get me
5 through the day."
6 That's just an example of the kinds of
7 things that I think everybody should be doing to
8 really make sure that these are fit-for-purpose
9 results.
10 DR. MALAMUT: I'm hopeful that you get
11 meaningful input on a hundred percent, but what
12 would you say your average has been? How often do
13 you get something that makes a meaningful change to
14 the protocol?
15 MR. LEVENTHAL: It's hard to say across the
16 entire portfolio, but we get meaningful input on at
17 least 60 to 70 percent of our studies, where we'll
18 go and we'll make some tweak in our protocol. The
19 nice thing about this, though, is -- as you all
20 probably know -- most protocols are written
21 historically, meaning that a protocol gets
22 typically based on things that were done in

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1 precedent before it, and many times the eligibility
 2 criteria get included in protocols just based on
 3 historical precedent, which may or may not be the
 4 right thing to do.
 5 We've done some foundational changes based
 6 on patient input, where the entire portfolio is
 7 affected. We've decided, okay, we're going to take
 8 this battery of exclusion criteria out of all of
 9 our studies because they're no longer relevant.
 10 That makes a big difference, so we've started
 11 addressing those kinds of things as well. I hope
 12 that answers your question.
 13 DR. MALAMUT: No, that's great. Thanks a
 14 lot, David.
 15 DR. KERNS: Thank you. We're going to take
 16 two more questions. I hope this doesn't back us up
 17 too much.
 18 First of all, Laura Forsythe.
 19 DR. FORSYTHE: Yes. Good morning. That was
 20 really interesting, and I think my question
 21 actually follows nicely from the previous one.
 22 I was just wondering what conversations, if

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1 any, you all have about return on investment. As a
 2 person, where part of my job is to try to figure
 3 out how do we understand and communicate the return
 4 on investment of engagement, I'm actually a little
 5 jealous sometimes of my colleagues who work in
 6 other points on the translation continuum, where
 7 there might be more of an opportunity to really
 8 talk about return on investment.
 9 I can put an example on the chat of
 10 something that the folks at Citi did a few years
 11 ago related to investment in engagement versus the
 12 return when you avoid terminated protocol or some
 13 other things like that. And I wondered if you
 14 could speak to beyond the moral commitment that
 15 Pfizer has and how you all think about return on
 16 investment, and if you're examining that in some
 17 way.
 18 MR. LEVENTHAL: Well, we were authors on
 19 those expected net present value papers done by
 20 Citi, so we believe it. The evidence is there,
 21 that by engaging with patients, if you
 22 reduce -- just one protocol amendment can run a

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1 minimum of a quarter of a million dollars. Those
 2 are the industry benchmarks we had done in that
 3 research. The value is really there.
 4 The other thing that we did is we created
 5 that online tool to quickly be able to assess that
 6 return on engagement in a way that's really
 7 palpable for sponsors. I would recommend anyone to
 8 go out and give that tool a try. Then of course,
 9 with all models, it makes a series of assumptions.
 10 But when we did that work, the assumptions were not
 11 crazy. They all more or less made sense, and we're
 12 in keeping with what we had seen that CitiCorp had
 13 done and our own internal work.
 14 So we don't necessarily have to do the
 15 return on investment modeling internally to Pfizer
 16 any longer because we've now instantiated it, but
 17 understand that there are other places that do. We
 18 do a retrospective analysis, though, on each of the
 19 studies and say, "What did we change?" And it's
 20 hard to do a head-to-head, where we run the study
 21 without it and we run the study with, but we try to
 22 go back and say, "Well these were things that we

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1 think were meaningful."
 2 DR. KERNS: Thank you both.
 3 I'm aware of the time, and I want to keep
 4 the agenda flowing. I apologize to Isabel Jordan
 5 and Sean Mackey, whose hands are up, and there were
 6 a couple comments in the chat. If you wouldn't
 7 mind saving those until the discussion after the
 8 presentations, I'd greatly appreciate it.
 9 Isabel, anything you'd like to ask that's a
 10 clarifying question or is it ok to wait?
 11 MS. JORDAN: It can wait till later. That's
 12 fine.
 13 DR. KERNS: Thank you very much.
 14 Alright. Let's move on then. Thank you for
 15 those comments, and thank you, David, again.
 16 MR. LEVENTHAL: Thank you.
 17 DR. KERNS: Next up is a panel of Regulatory
 18 Agency Perspectives in Engaging Patient Partners
 19 and Other Stakeholders in the Planning and Conduct
 20 of Pain Clinical Trials. First up is Nathalie
 21 Bere. She's the patient relations coordinator for
 22 the European Medicines Agency in Amsterdam, The

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1 Netherlands.
 2 Ms. Bere?
 3 Presentation – Nathalie Bere
 4 MS. BERE: Good morning, good afternoon,
 5 everybody; a pleasure to be here. I have a few
 6 slides to show, so I'm not sure if they can be
 7 brought up. Great. Thank you.
 8 I'm just going to share with you some
 9 experience that we have at the European Medicines
 10 Agency here in Europe for engaging with patients.
 11 For those who don't know, obviously, the EMA is the
 12 European regulator for medicines across Europe.
 13 It's taken us some years, but we have now
 14 developed a whole system whereby patients are now
 15 fully integrated in all aspects of our work along
 16 the whole medicines regulatory life cycle, through
 17 the presubmission procedures, the evaluation of the
 18 medicines, and then right on into the
 19 pharmacovigilance aspects as well. They are
 20 committee members; voting members. They
 21 participate in ad hoc expert meetings. We do
 22 larger public hearings. There are various

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1 different ways they get involved, and the next
 2 slide will highlight that a little bit.
 3 It's really, as I say, expanded over the
 4 years. What we try to do is start out slowly, do
 5 pilots, work with the patient community and the
 6 patient organization, and work to find out what
 7 works best for everybody involved so that it really
 8 is an optimal way for getting them on board,
 9 obviously, into a rather scientific regulatory
 10 arena, but allowing that to be conducive to really
 11 get very good information from them and for them
 12 also to feel comfortable.
 13 Here, overseeing how they are involved,
 14 they're full voting members on the management board
 15 on some of our committees. We have a working party
 16 of patients for the PCWP. We also have one of
 17 healthcare professionals and we often meet
 18 together. We have joint meetings with them because
 19 we found that, obviously, a lot of the topics are
 20 common, and they actually like to be able to hear
 21 from each other directly and have a debate, a lot
 22 of consultations in writing, workshops, and things

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1 like that, and then also the individual experts.
 2 You can see here the activity depends on
 3 what they represent. Either they represent
 4 themselves if they're living with a
 5 condition -- and we're talking about a specific
 6 medicine assessment, so there they bring their own
 7 experience to that discussion or the meeting -- and
 8 other times they're representing their particular
 9 patient organization, obviously often
 10 therapeutic-wise, or they could be representing
 11 their whole community as they do in committee
 12 membership.
 13 Over the years, the numbers of patients
 14 involved has increased. We try to be transparent
 15 about this, and we publish every year annual
 16 reports. We publish all of the documents, so that
 17 it's fully clear how we engage.
 18 I touched upon this a little bit earlier.
 19 They really do contribute directly into the
 20 scientific discussions. Obviously, their role is
 21 different than the scientific experts, but they get
 22 involved in the presubmissions; the scientific

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1 advice procedures; the expert meetings during the
 2 evaluation of the different medicines; written
 3 consultations; stakeholder meetings; public
 4 hearings; et cetera, et cetera.
 5 They also review all of our written
 6 information, and I think this is also very
 7 important because we need to make sure that we're
 8 writing everything in a lay language and it's
 9 understandable. So from package leaflets to safety
 10 communications, et cetera, they review all of them.
 11 Here, I just really wanted to be a little
 12 bit more specific for you, and I think you might
 13 find this interesting. One of the ways that they
 14 get involved is our scientific advice and protocol
 15 assistance procedures. These are procedures where
 16 pharmaceutical companies/developers can come to the
 17 EMA and ask for advice on the development plan.
 18 It's called protocol assistance when they're
 19 developing an orphan product, obviously, for a rare
 20 disease. That's the only difference.
 21 Patients are involved in a lot of these
 22 procedures, so of course we want to see does it

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1 make a difference, what's the impact, and is there
2 value for everyone involved. So we carried out a
3 survey over the last three years, which involved
4 about 300 of these procedures. We sent out
5 questionnaires to the regulators involved, as well
6 as the patients when they participated. The
7 participation can either be in a face-to-face
8 meeting, or virtual, or it can be in writing. It
9 depends if there is a meeting or if there isn't.

10 We really asked them to let us know when the
11 patients participated; firstly what kind of things
12 did they bring to the discussion, and then how
13 often did that make a difference. Did it just
14 generate discussion or was there an actual tangible
15 difference to the final advice letter that then is
16 given to the developers?

17 You can see here, on the right, the
18 different areas where patients contributed, so it
19 really is on tangible points -- sorry, it's
20 probably a bit little -- on endpoints, population,
21 quality of life, standard of care, feasibility of
22 the study, and things like that, so really relevant

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1 points that they bring to it.

2 Then, overall, we found that in just over
3 half of the times when patients were involved,
4 comments that they brought resulted in further
5 discussion. So it generated discussion in the
6 meeting, and 20 percent of those cases then
7 actually led to a tangible difference or an
8 addition to the advice that is given back to the
9 company.

10 Importantly, in 90 percent of the cases when
11 there wasn't a difference, actually we found that
12 when we looked a bit deeper, it was because the
13 patients were actually agreeing with the proposed
14 plan. So I think it's important that it doesn't
15 mean they have to disagree or say something new for
16 it to be an impact for us; it's also impactful that
17 they agree with the proposed plans, and it seems
18 feasible, et cetera, from their side.

19 I think this is just a really nice example,
20 and it's not always easy to get this kind of data
21 on the value and impact of patient involvement, or
22 any expert involvement. When you're looking at

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1 these kind of involvements where it involves
2 joining meetings or giving input in writing, it's
3 very subjective to try and determine how much did
4 somebody say and how much impact did that have, but
5 I think here we managed to get some data, which
6 we're going to publish a paper shortly.

7 We feed this back to the patients involved
8 as well so that they understand that it is valuable
9 having them there, and it does make a difference,
10 and it's not just a tickbox. And it helps us
11 understand, as well, that we're doing it in the
12 right way that is allowing us to get this
13 information in.

14 I just added another one we do. We do
15 review the number of comments that people make on
16 those documents I mentioned earlier. We did that a
17 couple of years ago, and about 50 percent of their
18 comments made a change to the EPA [ph] summary,
19 which is a document on the oval EMA summary.

20 In the next and last slide, it was just to
21 summarize that we've developed various ways that
22 patients can engage in the regulatory activities at

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1 EMA. It does make a difference. They bring data
2 that we don't have: the aspects of living with a
3 condition; what their unmet needs are; and what
4 they're looking for in a new treatment or a new
5 medicine that helps bridge that gap. It allows us
6 to be transparent and gain trust as well with
7 patients and with the community.

8 So yes, value demonstrated, and I think at
9 the end we've seen that it does lead to, hopefully,
10 more meaningful outcomes for everyone. So that's
11 my slides. Thank you.

12 DR. KERNS: Thank you very much, Nathalie.

13 We're going to go right on to our next
14 presentation, and we'll have three in this series,
15 and then come back to questions after that.

16 Next up, actually, is Captain Robyn Bent.
17 Captain Bent is director of the Patient Focused
18 Drug Development program in the Center for Drug
19 Evaluation and Research at the FDA in Silver
20 Spring, Maryland. Captain Bent was uncertain about
21 her ability to get here for this presentation, so
22 actually we have a pre-recorded presentation from

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1 Captain Bent.
 2 Carlos, if you'd cue that now.
 3 Presentation – Robyn Bent
 4 CAPT BENT: Thank you so much for having me.
 5 I'm Robyn Bent. I work for the Center for Drug
 6 Evaluation and Research's Patient Focused Drug
 7 Development program here at the U.S. FDA, and I'm
 8 really happy to be here to talk to you today about
 9 FDA's focus on including the voice of the patient
 10 in medical product development and our perspective
 11 on the importance of patient centricity.
 12 I'm going to talk about how we're
 13 encouraging that, and then I'm going to move on to
 14 talking about the value to researchers of adopting
 15 a more patient-centered approach to drug
 16 development and drug safety from FDA's perspective.
 17 Before I talk about patient-focused drug
 18 development, I'm going to define it.
 19 Patient-focused drug development is really a
 20 systematic approach to help ensure that patients'
 21 experiences, perspectives, needs, and priorities
 22 are captured and really meaningfully incorporated

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1 into drug development and evaluation. I'm going to
 2 start by framing the conversation.
 3 The purpose of this slide is to really show
 4 some key areas where patient input can be valuable,
 5 but this isn't to imply in any way that these are
 6 the only areas in which patient input can be
 7 valuable. For example, in the early stages of
 8 clinical development, patient input can help
 9 researchers and FDA really understand what impacts
 10 of a disease and of treatment matter most to
 11 patients and help us figure out how to best measure
 12 them.
 13 During the planning and conduct of clinical
 14 trials, patient input can help us to understand
 15 what aspects of clinical trials can be better
 16 tailored to meet the needs of patients who may
 17 participate in the trials. During the premarket
 18 review stage, we can use data obtained directly
 19 from patients, such as patient-reported outcome
 20 measures or patient preference studies, to inform
 21 FDA benefit-risk assessments. In the postmarket
 22 setting, patient input can help us to understand

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1 how to best communicate information to patients and
 2 prescribers in order to facilitate decision-making.
 3 While FDA has a long history of patient
 4 engagement, our Patient Focused Drug Development
 5 program really began with our patient focused drug
 6 development, or PFDD, meetings. We hold these
 7 meetings to hear directly from patients, patient
 8 advocates, and caregivers with a specific condition
 9 about the symptoms that matter most to them; the
 10 impact the condition has on patients' daily life;
 11 patients' experiences with currently available
 12 treatments; what patients would value most in a new
 13 treatment; and what factors they would consider
 14 when determining whether or not to participate in a
 15 clinical trial.
 16 These meetings also have the potential to
 17 address areas of unmet need for the patient
 18 population and to give us an idea where we might
 19 need to identify or develop tools that assess
 20 benefit of potential therapies. It can also raise
 21 awareness and channel engagement within the patient
 22 community.

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1 What we've heard from these meetings really
 2 reinforces that patients are experts in what it's
 3 like to live with their condition. We've learned
 4 that the chief complaints we hear at these PFDD
 5 meetings are often not being factored explicitly
 6 into drug development plans, and that, often,
 7 they're not being measured in clinical trials.
 8 We've learned that patients want to be as active as
 9 possible in the work to develop and evaluate new
 10 treatments, and that the most obvious symptom of a
 11 disease or illness is not always the most
 12 bothersome.
 13 One example of a meeting that we held was a
 14 meeting on chronic pain, which was held back in
 15 2018. For our chronic pain meeting, we had more
 16 than 120 patients and caregivers in the room and
 17 over 300 participants online. We received over
 18 2400 comments to our public docket.
 19 In order to get this level of participation,
 20 we reached out to a number of patient groups and
 21 medical facilities, asking them to share
 22 information on the meeting with their members. We

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1 worked really hard to accommodate our meeting
2 participants so that they felt they could attend
3 the meeting. We heard from patient groups that
4 participants may need areas to rest or to lay down
5 in the event that their pain got overly severe, so
6 we reserved additional rooms to support them, which
7 are things that we may not have thought of if we
8 hadn't worked with the patient groups and really
9 listened to their feedback. The Voice of the
10 Patient report from that meeting is available on
11 our PFDD website.

12 In addition to including patients in the
13 drug development process itself, FDA also
14 encourages the inclusion of patients or their
15 caregivers when developing fit-for-purpose clinical
16 outcome assessment, and this is critical. And not
17 only do we talk about the importance of doing this
18 and have an entire guidance series focused on it,
19 we're actually doing these ourselves.

20 As part of our Standard Core Clinical
21 Outcome Assessments and Related Endpoints Grant
22 Program, we're funding the development of a core

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1 set of measures to assess acute pain in infants and
2 young children. This program really leans heavily
3 on the feedback from patient caregivers who work
4 with our grantees as active members of the team, as
5 members of the external technical advisory
6 committee, and of course other caregivers who are
7 currently participating in the qualitative concept
8 elicitation portion of the grants.

9 So while you're reading this, I just want to
10 talk a little bit more about the value of patient
11 input because in addition to improving the science
12 of clinical research, it can have other effects.
13 There's literature that supports that working with
14 patients and patient groups can decrease trial
15 attrition.

16 It can increase understanding of barriers to
17 trial enrollment and participation and increase
18 researchers' ability to recruit diverse
19 populations. It can increase the rate of
20 enrollment into trials, and it can decrease the
21 number of protocol amendments by identifying
22 potential problematic exclusion criteria or aspects

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1 of the protocol that may decrease willingness of
2 patients to participate in the trials. I think
3 this is all really important information.

4 Finally, this slide provides you with a link
5 to our Patient Focused Drug Development home page,
6 as well as a link directly to our FDA-led PFDD
7 meetings. Thank you so much for your time, and I
8 look forward to your questions later in the
9 meeting. Thank you.

10 DR. KERNS: Terrific.

11 Next up, we're going to hear from Dr. Alysha
12 Croker. Dr. Croker is the manager, Office of
13 Pediatrics and Patient Involvement; the Center for
14 Regulatory Excellence Statistics and Trials, or
15 CREST; the Health Products and Food Branch of
16 Health Canada, Government of Canada, based in
17 Ottawa, Ontario, Canada.

18 Dr. Croker?

19 Presentation – Alysha Croker

20 DR. CROKER: Wonderful. Thank you so much.

21 Hello, everyone. Thank you for including
22 Health Canada in this panel discussion. I'm really

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1 honored to be here to talk to you a little bit
2 about Health Canada's patient involvement
3 activities. As a note maybe just at the beginning,
4 Health Canada has just started its work in this
5 area, so as you'll see, some of our slides were not
6 quite as far ahead as the FDA or the EMA on this
7 topic.

8 Just quickly for those of you who may not be
9 familiar with the internal structure of Health
10 Canada, I'll just take a second to orient you. For
11 those who are aware, Health Canada's responsible
12 for helping people in Canada maintain and improve
13 their health, and we do this in a lot of ways. One
14 of those ways, of course, is by regulating the
15 import and sale of drugs in Canada. That's the
16 Health Products and Food Branch that acts as
17 Canada's health regulator and is the branch that's
18 responsible for authorizing health products based,
19 of course, on their safety, efficacy, and quality.

20 My office, the Office of Pediatrics and
21 Patient Involvement, is within the HPFB, or Health
22 Products and Food Branch, and we work across the

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1 branch and a number of files, including integrating
2 patients' expertise across our regulatory and
3 policy work. Robyn's already talked a little bit
4 about patient-focused drug development. I've put
5 devices in there, too, because I think the premise
6 of PFDD applies to medical devices as well.
7 Just to mention quickly, there's obviously
8 an increasing need to draw on patient knowledge,
9 experience, and expertise in order to really
10 understand the day-to-day realities of living with
11 a particular disease; what the comfort level of
12 patients with this disease might be to risk; what
13 clinically meaningful endpoints look like to these
14 patients; and whether unmet medical needs are being
15 met through a particular drug, or device, or trial,
16 and that type of thing.
17 Robyn also had a slide very much like this,
18 so I don't need to go over this in much detail,
19 other than to say that there are a number of ways
20 and places that patient-focused drug and device
21 development can be integrated across the life
22 cycle. Focusing on trials, here I've bolded the

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1 text in aqua just to draw your attention to a
2 couple of examples.
3 As I mentioned, Health Canada's patient
4 involvement activities are still in the initial
5 stages. We're in the process of pulling together a
6 patient involvement strategy, which will aim to
7 have regulatory and policy decisions being formed
8 by the patients who are impacted by those
9 decisions, and then we'd aim to accomplish that by
10 finding ways to systematically integrate meaningful
11 patient involvement activities across the drug and
12 medical device life cycle.
13 As we've already heard from the previous
14 panel members, we have a lot of wisdom and
15 experience on this topic internationally. Both the
16 FDA and the EMA have already implemented wonderful
17 patient activities that we now have the benefit of
18 learning from in Canada.
19 In terms of pain, Health Canada doesn't
20 currently have any ongoing patient involvement or
21 initiatives related to that topic, but we're always
22 open to working with patients in the broader

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1 community to identify and address issues that fit
2 within our mandate and that are meaningful to
3 patients. So I'll stop there, and I look forward
4 to the discussion.
5 Clarifying Q&A
6 DR. KERNS: Thank you, Dr. Croker, very
7 much.
8 Let's take one or two questions before we
9 move on to our next presentation, and try to keep
10 them to clarifying questions if you can.
11 Lee Simon?
12 DR. SIMON: Hi, everyone. I was wondering,
13 as it relates to EMA in particular, in that you all
14 incorporate patients into some of your scientific
15 discussions, how do you vet them for potential
16 conflicts of interest to be able to participate in
17 such a thing?
18 The FDA on advisory panels goes through a
19 whole series of complicated vetting procedures to
20 ensure no conflicts of interest. How do you do
21 that for your individual scientific committee
22 meetings as you use patients and incorporate

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1 patients into giving such great advice? How do you
2 do that?
3 MS. BERE: Well, thank you very much for the
4 question. Yes, indeed, we also have a whole system
5 of vetting individuals before they can get
6 involved. They have to fill in various forms. We
7 have a declaration of interest form, so they have
8 to highlight any interactions or any interests they
9 have with pharmaceutical companies, they or their
10 families, or any links, which is then submitted.
11 They have to fill in other various forms,
12 and essentially they have to become what we call an
13 EMA expert. These forms are then put into an
14 expert database, and then actually we do publish
15 all of the experts' names and certain level of
16 detail so that we're transparent.
17 If they become an expert, this lasts for a
18 year and they can renew it. And then each time we
19 have a specific activity, their declaration of
20 interest is then reviewed for that particular
21 activity, that particular product we're talking
22 about, again, to make sure there is no potential

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1 conflicting interests.
 2 So hopefully that answered your question.
 3 We're lucky that it's a pretty online system. It
 4 does still take some time to do, but it's an online
 5 system of various forms to fill out.
 6 DR. KERNS: Thank you. Thank you, Lee, for
 7 the question.
 8 Penney Cowan? We'll take one more question
 9 from Penney, and then we'll move on.
 10 Penney?
 11 MS. COWAN: Thank you. And thank you, all,
 12 for your presentations. I have one for Ms. Bere.
 13 The people that take part in your panels are
 14 not your average consumer. So my question is, do
 15 you ever go out into the communities once they
 16 review all the materials, the past [inaudible --
 17 audio gap] -- focus groups, and inner cities, and
 18 rural areas to see if they also understand and
 19 comprehend the kind of information -- I mean, the
 20 very end user, and they're not the ones -- they're
 21 the ones who are probably taking it or choosing not
 22 to, because they read -- I mean, do you ever go out

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1 into the communities and do those focus groups to
 2 really get their feedback? Thank you.
 3 DR. KERNS: I think the question may have
 4 been for -- yes, please?
 5 MS. BERE: Was it for me? Sorry. I didn't
 6 hear --
 7 DR. KERNS: Well, I think anybody, but --
 8 MS. COWAN: Yes --
 9 (Crosstalk.)
 10 DR. KERNS: -- I think she called you out.
 11 MS. BERE: It was? Okay. Thank you.
 12 MS. COWAN: I was trying to do it quickly.
 13 MS. BERE: Sure. No. Thank you for the
 14 question as well.
 15 We actually do try to reach out to the
 16 community. I think it's really difficult to get to
 17 the hard-to-reach patients, so we rely, on the one
 18 hand, on the patient organizations across Europe.
 19 They really have a good outreach with the patient
 20 community. When we get them to get patients
 21 involved, we also try and tell them to reach out,
 22 really as much as they can, within their community.

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1 So whenever we have an activity and we're
 2 advertising for it, to reach out to those patients
 3 as well.
 4 We also have a registration system for
 5 individual patients. Not everybody is part of an
 6 organization. We also try and use social media and
 7 things like that to reach out and get the
 8 individual patients to register in a database that
 9 we have; and then when we have these activities, we
 10 then try and do a mix of reaching out to the
 11 individuals, and then also reaching out to the
 12 organizations.
 13 We have a big challenge in Europe in terms
 14 of language because, of course, our working
 15 language is English, and in Europe there are many
 16 different languages spoken. So I would say that
 17 that is a key challenge as well.
 18 DR. KERNS: Thank you very much. Thank you
 19 for the question, Penney. We'll have more time for
 20 discussion; just a great panel. Thank you each for
 21 terrifically focused and comprehensive
 22 presentations.

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1 I'm going to turn next to our next topic on
 2 the agenda. This is the how tos related to
 3 Measuring Patient Engagement in the Planning,
 4 Conduct, and Dissemination/Implementation of
 5 Clinical Pain Research. This will be presented by
 6 Dr. Laura Forsythe. She's director of Evaluation
 7 and Analysis at the Patient-Centered Outcomes
 8 Research Institute, PCORI, in Washington, DC.
 9 Dr. Forsythe?
 10 Presentation -- Laura Forsythe
 11 DR. FORSYTHE: Thank you very much.
 12 Well, I guess we've just moved to afternoon
 13 on the East Coast. Good afternoon, everyone. It's
 14 a real pleasure to be here. On a personal note,
 15 I'm actually thrilled to be presenting at a meeting
 16 focused on pain research. While I'll be, really,
 17 drawing on my experience in this talk from my
 18 nearly decade at PCORI, I actually started my
 19 doctoral training to be a clinical health
 20 psychologist, studying management of chronic pain
 21 with Beverly Thorn. So more than usual, I wish
 22 this meeting was in person because there's a bunch

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1 of you I'd love to say hello to and catch up, but
2 here we are, measurement of engagement in research.
3 What I want to do is try to explore four
4 questions about measurement of engagement in
5 research: why is it important; how is it complex;
6 where are we now as in what do we have with respect
7 to measures; what do we know; and then what does it
8 mean for us? And, really, I'm thinking "us" as
9 research teams in the field, as PCORI and other
10 funders, and as a collection of colleagues trying
11 to advance clinical pain research.
12 There are kind of three main sources I'm
13 going to draw on to talk with you about this today.
14 There are two systematic reviews about measures of
15 engagement, one by D. Bowen and colleagues from
16 2017 and another by Antoine Boivin and his
17 colleagues in 2018.
18 PCORI has in progress right now a landscape
19 review and gap analysis about measures of
20 engagement in research, and we're trying to answer
21 basically three questions there: What measures are
22 needed for and by whom? What's the current state

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1 of measures available and how do those aligned with
2 stakeholder needs? And then, how do we address
3 measurement gaps? We commissioned this project and
4 collaborate on it with Tom Concannon and his
5 colleagues at RAND.
6 How we are learning about measures through
7 this project, there are three core components: key
8 informant interviews with a diverse set of
9 stakeholders that have experience and interest in
10 measuring engagement and research; literature
11 review; and then coming soon, a synthesis of all of
12 that.
13 If this meeting were in another couple
14 months, I would have, even then, a lot more to say,
15 really, about interpretation of where we're at with
16 measures, but I'll give you some early lessons so
17 far. We engage patients and stakeholders
18 throughout this project, particularly through a
19 multistakeholder project advisory group that
20 advises on each stage of the work.
21 I want to talk a little bit, briefly, about
22 why measurement of engagement is important. I

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1 expect you all actually already have your own ideas
2 about this, but I think it's helpful to start with
3 some of the grounding assumptions that I'm bringing
4 to this conversation. Just as a reminder, you
5 heard from Dr. Goertz and Dr. Carman from PCORI on
6 the first day of the meeting about PCORI's
7 expectation that engagement to us means the
8 meaningful involvement of patients throughout the
9 entire research process.
10 You heard them talk about how PCORI expected
11 that engagement would lend research that is more
12 relevant, high quality, and more likely to be used
13 in decision-making. You also heard what we know so
14 far about engagement approaches, how to do it well,
15 and the impacts engagement can have and the
16 evidence gaps that remain.
17 I think that's really the background of why
18 engagement is important, but then measurement of
19 engagement really is a critical tool both for
20 engagement science, studying engagement
21 systematically, and also for the practice of
22 engagement.

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1 We need standardized, validated assessments
2 to help us move from a conversation about lessons
3 learned and promising practices to more evidence
4 about the most effective approaches to engagement
5 that are acceptable to the people involved and
6 aligned with their values and needs and preferences
7 and the needs of research. People committed to
8 engagement really also still want to understand how
9 to best do it so that we can maximize the benefits
10 of working together.
11 We also need these measurement tools to help
12 further our understanding of the impact of
13 engagement, not only in the research, but the
14 people involved and health care and health
15 outcomes. This is not only for skeptics who want
16 to hear more about the costs and benefits and
17 risks, but even in the context of commitment to
18 engagement as the right thing to do, this kind of
19 information really can help us understand what
20 success might look like and how we get there.
21 When we think about engagement practice,
22 measurement is really critical to helping teams

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1 understand how well they are engaging, are things
 2 playing out as they intended, and where can they
 3 improve. It's really a valuable piece, ultimately,
 4 to help facilitate making engagement easier and
 5 more widespread.
 6 Let's talk about how is it complex. I just
 7 want to acknowledge that all measurement is
 8 complex, but I want to give you some insights
 9 specifically into how measurement of engagement in
 10 research is complex.
 11 First, we've heard a lot at this meeting
 12 about the wide variation in engagement terms,
 13 definitions, and approaches. We know that the
 14 requirements, guidance, and assumptions about what
 15 is sufficient, what is normative, and what is
 16 acceptable, those are different for different
 17 funders, different consumer groups, and others
 18 involved.
 19 Engagement by design is tailored to
 20 cultures, to settings, to research areas, and
 21 that's necessary and helpful variation. Also, all
 22 those differences affect how people think about and

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1 can see of engagement, what they feel should be
 2 measured, and how it should be measured.
 3 Another thing to think about is it's
 4 tempting, but we've learned it's not really
 5 accurate to put whole teams or whole projects in
 6 one single category about engagement, successful or
 7 engaging like this, because engagement is also
 8 dynamic. It varies over time within and across
 9 projects.
 10 It's a bit stating the obvious, I think, but
 11 I just want to remind people that in the context of
 12 measurement, engagement is affected by factors at
 13 multiple levels. We have people interacting
 14 together on teams working in the context of
 15 projects or research programs; working within and
 16 across different institutions, cultures, and
 17 funders, and all of those things play a role.
 18 Of course, measurement of engagement, like
 19 engagement, is a multistakeholder process, and
 20 there are a couple of things to highlight here.
 21 The first is that different stakeholder groups have
 22 different priorities. They have different

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1 questions about engagement and different priorities
 2 for what gets measured, how it gets measured, and
 3 how that information is used.
 4 There are of course questions that span
 5 stakeholder groups, but there are also different
 6 lenses through which different stakeholders look at
 7 these kinds of questions. For example, many
 8 patients went to understand if they can have a
 9 meaningful impact on the research and the extent to
 10 which they felt supported and prepared to engage as
 11 they intended. Many researchers have questions
 12 about how do I do engagement effectively and
 13 efficiently and how will it affect my research in a
 14 more proximal sense. Policymakers often have
 15 questions about how inclusive is engagement, how do
 16 we make it more inclusive, and what's the impact of
 17 engagement on health, more broadly.
 18 Also, just to keep in mind that perspective
 19 matters, when you have people from different
 20 perspectives involved in dynamic situations, they
 21 may be coming from different places, different
 22 backgrounds, and different value structures. As we

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1 move forward with measurement of engagement, it's
 2 really critical to think about whose perspectives
 3 are we capturing; whose perspectives matter; how
 4 and why might they differ; and what do differences
 5 in perspective really tell us.
 6 I want to move now to tell you a little bit
 7 about where we are in terms of measurement.
 8 Clarity of goals and definitions really are
 9 necessary for measurement evaluation. We've talked
 10 about not only do we lack a fully shared language
 11 about the core components of engagement and what
 12 they mean, which is needed to help us better speak
 13 to each other about the ideas about what should be
 14 measured and what we're really capturing, we also
 15 need more measurement frameworks to provide a
 16 strong theoretical foundation for measure,
 17 development, and application.
 18 One of the steps PCORI is taking through our
 19 current project to try to begin to address this
 20 issue is developing a taxonomy or an inventory of
 21 the concepts within engagement that we feel we need
 22 to know about and to help define what they cover,

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1 how they group together, and why they're important.
 2 We've identified four broad domains, and
 3 would just say, as I alluded to earlier, this is a
 4 project in progress. So this is a sneak peek, and
 5 these things may tweak some, and we've identified
 6 four big domains. I'm sharing a couple examples of
 7 concepts that map to each of those domains to help
 8 give you a sense of what we're learning here.
 9 For example, engagement content really
 10 covers the who, what, and why of engagement, and
 11 this includes things like the stakeholders and
 12 research involved or the underlying principles like
 13 equity; whereas context is really about when and
 14 where, in a broad sense, and encompasses things
 15 like community and culture, as well as things like
 16 a research team and organizational structures
 17 within which engagement is happening.
 18 Process is really about the how. These are
 19 things like group dynamics, power sharing, and the
 20 intensity of engaging activities. Outcomes is
 21 about the so what that we've been talking about in
 22 terms of things, including the patient and partner

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1 experience, the impact on research, and ultimately
 2 as well on researchers, research institutions, and
 3 patient and population health.
 4 Two things to note here is, first, the
 5 taxonomy is really just a start. We are not yet at
 6 the point of a measurement framework or model that
 7 would really give guidance or expectations about
 8 what must be measured, how it must be measured,
 9 what must be achieved, but this is a start toward
 10 some shared language.
 11 Second, even talking about shared language
 12 is actually really tricky because one of the things
 13 we've learned from our project advisory group and
 14 other work in this project is that one person's
 15 process is another person's outcomes, and I think
 16 that's, again, back to perspective. Kristin, who
 17 you all heard from earlier, has been really helpful
 18 in pointing that out.
 19 So where are we now? The big bottom line is
 20 there are really limited measures of engagement and
 21 research available right now. Our estimate of our
 22 project in progress is there's about 35 to 40

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1 published instruments. The majority are drawn from
 2 community engagement, and most focus on engagement
 3 processes and contexts. Relatively few focus on
 4 outcomes.
 5 Among that set of measures, there are some
 6 really meaningful limitations. Few report validity
 7 testing at all. Most that do focus on face
 8 validity. Other forms of content and measure
 9 validation are rare. Reliability testing is also
 10 rare, and there's really limited grounding and
 11 conceptual frameworks.
 12 I want to give you just one illustrative
 13 example of a measure that has gone through
 14 relatively more validation. This is really a
 15 spotlight on a PCORI project. Dr. Melody Goodman
 16 has led an effort to develop the research
 17 engagement survey tool and just published a short
 18 form in 2021. It assesses aspects of both quality
 19 and quantity of demonstration of engagement
 20 principles, things like sustainability and
 21 co-learning. Measure allows us to make comparisons
 22 of partner engagement across and within studies

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1 over time, and stakeholders were involved
 2 throughout the conceptualization, and development,
 3 and validation of these measures.
 4 Another key thing about the measures that
 5 are available now, though, are there's limited
 6 measures that engaged patients and stakeholders
 7 throughout the entire process. At least
 8 historically, many measures either lacked that
 9 engagement in the measure development or the
 10 engagement is really focused on a pilot phase. It
 11 was a very narrow use of partners in terms of
 12 thinking about the entire process,
 13 conceptualization, design, validation, and
 14 implementation. There are some more recent
 15 published examples that did a really good and
 16 thorough job of engagement in the measure of
 17 development, and I have some reference lists that
 18 include some of those at the end.
 19 Of course, knowing this, there's also a gap
 20 between what stakeholders want to measure and what
 21 they can currently measure. This is both because
 22 stakeholders are particularly interested in both

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1 engagement of process and engagement outcomes, and
 2 measures are really only focused on the process
 3 piece. It's also because even when we think about
 4 available measures within process, they have the
 5 limits that I was just discussing.
 6 I want to spend just a moment telling you
 7 about where we are now with respect to measures of
 8 engagement in clinical pain research specifically.
 9 I think it won't be surprising that while there are
 10 examples of engagement in pain research where the
 11 engagement is strong, the science of engagement in
 12 measured development is limited in the context of
 13 clinical pain research specifically. So it's
 14 really an opportunity to ask ourselves what from
 15 other settings is generalizable or transferable to
 16 pain research, and what elements, if any, are
 17 really unique to engagement in pain research?
 18 I would expect that there are a lot of core
 19 elements with respect to measurement of engagement
 20 that might be generalizable and that there are some
 21 unique things we might think about in terms of
 22 outcomes, for example.

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1 Relatedly, I do want to also put a nod to
 2 our colleagues in other fields. PCORI really
 3 focuses on clinical effectiveness research, which
 4 is very far down the translation continuum, but
 5 there are colleagues on other points on that
 6 continuum that are also helping to contribute to
 7 this conversation in ways that are relevant to pain
 8 research. For example, the group paradigm in
 9 Europe is focused on engagement for medicines
 10 development and is doing some nice work putting out
 11 things like metrics for engagement in measure
 12 development that also could be a precursor to then
 13 thinking about what we measure and how we measure
 14 it.
 15 What does that mean for us as research
 16 teams, as funders, and as a field trying to make
 17 progress? The first thing I want to highlight is
 18 for research teams out there, I want to talk for a
 19 minute about creating a culture of continuous
 20 improvement. This idea really takes a page from
 21 quality improvement models that value teamwork,
 22 peer review, recognizing fallibility, and viewing

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1 errors as opportunities.
 2 I thought that Christine and Isabel
 3 yesterday demonstrated those ideas so beautifully.
 4 Even in the absence of a plethora of measures about
 5 the engagement process, there are still things
 6 teams can do to establish this culture of
 7 continuous improvement that starts with
 8 establishing shared vision of goals, roles, and
 9 expectations, and includes revisiting those and
 10 maintaining an ongoing dialogue, a qualitative
 11 understanding, and a conversation about what did we
 12 want to achieve; what was our vision for how we
 13 would work together; and how are we doing on living
 14 that out; and also, importantly, closing the
 15 feedback loop by recognizing the contribution of
 16 partners to the projects, very explicitly?
 17 For PCORI, other funders, and the field,
 18 there's obviously still more work to be done. Our
 19 current landscape review and gap analysis will add
 20 to this conversation about the concepts,
 21 constructs, and measures, and we plan to next
 22 collaborate with stakeholders and technical experts

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1 to identify and prioritize measures for use and
 2 also measure constructs where new or revised
 3 measures are needed. Certainly contributions from
 4 others, including people working in pain research,
 5 can accelerate our progress and thinking there.
 6 Then, we obviously need more well-developed
 7 measures of engagement. We need to figure out
 8 valid ways to measure important ideas and then do
 9 the work to ensure that they are measuring what we
 10 intend. We also need to continue to expand on the
 11 more recent trends to engage patients and
 12 stakeholders throughout the entire cycle of
 13 measure, development, and use. As we get into
 14 measure implementation and use, we need to take the
 15 time to consider what have we learned from those,
 16 what do they help us achieve, and how can we
 17 continue to improve those measures.
 18 I just want to offer one more invitation to
 19 let PCORI know about your priorities for the
 20 science of engagement, and in particular because
 21 there are questions in this request for information
 22 about measure development, use, and priorities

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1 there. You can respond to that RFI through
 2 November 19th.
 3 I will just quickly reiterate the main
 4 summary, conclusions, and opportunities.
 5 Measurement of engagement is a critical tool for
 6 both engagement science and practice. It is
 7 complex for reasons inherent to engagement.
 8 Different stakeholder groups want to measure
 9 different aspects of engagement and often have
 10 different priorities. There's more we can do to
 11 make progress to prioritize the constructs where we
 12 need more measures and validation, and there's, of
 13 course, a gap between what stakeholders want to
 14 measure and what they can measure.
 15 We need more measures that are well
 16 validated, that are developed through full
 17 engagement, and that address those priority topics.
 18 A shared language and more measurement frameworks
 19 will help us facilitate both measure development
 20 and measure use.
 21 I just want to end by thanking my colleagues
 22 at PCORI, RAND, and our Project Advisory Group.

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1 They are critical to all of this work and thinking.
 2 Then I have a bunch of stuff for you all for later,
 3 which includes some summative references that I
 4 talked about; other references related to measures
 5 of engagement, including some specific measures
 6 that are newer and maybe still in the process of
 7 being validated; some references from PCORI that
 8 are about the science of engagement more broadly
 9 because they touched on some topics that have come
 10 up throughout this conversation; and some other
 11 resources for the same reason.
 12 Some of you all were asking great questions,
 13 and I thought, "Oh, this particular resource would
 14 help with that conversation," and that's it. I
 15 would love to continue the conversation this
 16 afternoon and offline, as you are interested.
 17 Thank you.
 18 Clarifying Q&A
 19 DR. KERNS: Thank you very much, Laura. .
 20 This was just terrific. I'm sure that this is
 21 going to help inform our discussions, and
 22 ultimately our recommendations. Chris, and I, and

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1 the planning committee all agree that issues around
 2 measurement at some level are the core of what we
 3 need to be doing at this point, so thank you very
 4 much.
 5 We have time. I'll take a question or two.
 6 John Farrar?
 7 DR. FARRAR: Yes. Thank you very much.
 8 Laura, that was an excellent presentation.
 9 I wanted to ask perhaps a difficult question. It
 10 may well be in some of these measure publications
 11 that I'm not familiar with.
 12 What is the outcome of the measure that
 13 you're using for participation? What is
 14 considered, by PCORI at least, to be active engaged
 15 participation? Does it need to go through to
 16 actual changes in the protocol or is it some other
 17 set of measures? Obviously, it may be dependent on
 18 the setting and the time, or the level of research
 19 that's being done.
 20 DR. FORSYTHE: I think I hear a couple
 21 things in your questions. There's one piece, which
 22 is what is PCORI's expectations for engagement in

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1 our funded projects and what does that look like?
 2 That's really about meaningful inclusion of people
 3 throughout the design, conduct, and dissemination
 4 of the study. Those roles look very different
 5 across all of our projects. They're structured in
 6 different ways. The teams look different. As
 7 Kristin said -- what day was that? Wednesday -- we
 8 didn't prescribe exact formulas, but we did put out
 9 a rubric with guiding principles and things that we
 10 expect the projects to do.
 11 PCORI is not yet at a point of having a
 12 measure of an outcome that means success for
 13 engagement. I think that comes back to the points
 14 about different stakeholders, perspectives, and
 15 what matters. We had ideas about some of the ways
 16 that we expected engagement to benefit the research
 17 when we set out in terms of relevance for end users
 18 and things like that, and have done -- it's
 19 referenced, in particular, in Dr. Goertz's
 20 presentation from the first day -- some work to
 21 examine what has been the contribution of
 22 engagement to our projects to things like relevance

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1 of the project, feasibility, and acceptability to
2 patients and people who would be participants.
3 So that's important, that we are committed
4 to looking for an understanding of how is
5 engagement contributing. I think the million-
6 dollar question that we're moving into next is how
7 do we really devise a variety of outcome measures
8 for engagement that cover the whole range of
9 outcomes that matter to stakeholders with respect
10 to engagement.
11 It includes the research project and the
12 design and conduct of the project. But it also
13 includes many things beyond that related to the
14 people involved; the experience they had partnering
15 on the project; their researchers, who they are,
16 how they go about research going forward, and the
17 culture of the institutions; and things like that
18 as well.
19 DR. FARRAR: Yes. I think it fits with your
20 comment, which is, I think, key here, that it's
21 complicated. Meaningful and what matters, it's
22 sort of a I know one when I see one, but it's

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1 really hard to define. And I'm simply pointing out
2 that it could be really hard to come up with a
3 single measure, or even a set of measures, that
4 gets at those features.
5 DR. FORSYTHE: I think that's a great point,
6 too, that I didn't make explicit, is that we are
7 not in pursuit of a single measure of engagement.
8 It's really a constellation of things that are
9 relevant at different points through a project life
10 cycle, or program of research life cycle, or a
11 relationship between groups of people who are
12 working together.
13 DR. FARRAR: Yes. Thank you very much.
14 DR. KERNS: Thank you very much, both of
15 you. And thank you particularly, Laura; a great
16 presentation and discussion, and we look forward to
17 everybody's participation in the relevant
18 discussion later.
19 We have one last session. This is a panel
20 presentation focused on Journal Reporting on
21 Patient and Other Stakeholder Engagement in the
22 Planning and Conduct of Clinical Pain Research.

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1 I'm pleased to welcome Dr. Mark Jensen. Mark is
2 professor and vice chair for research, Department
3 of Rehabilitation Medicine, University of
4 Washington, and editor-in-chief of Journal of Pain.
5 He's based in Seattle, Washington.
6 Mark, please go ahead.
7 Presentation - Mark Jensen
8 DR. JENSEN: My comments are going to be
9 very brief. I'm just going to make a few basic
10 points, and then hopefully that will leave time for
11 discussion about issues around reporting and
12 participation in stakeholder engagement in papers.
13 Just key issues to cover, in our journal we
14 want to, and we do, publish papers that report the
15 findings from research of the highest rigor, so
16 rigor is key. The impact of the paper is key, and
17 the methods and results must be clearly and
18 transparently described. Those are, really, the
19 key issues.
20 With respect to stakeholder engagement,
21 then, we know that clinical research does not
22 always have to have stakeholder impact to be both

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1 rigorous and impactful, but it often will. As
2 Dr. Forsythe was talking about, it's key to the
3 impact and rigor of many, many studies.
4 We know that stakeholder involvement is
5 increasingly expected by sponsors. The
6 Administration for Community Living, which funds a
7 great deal of our research, requires that
8 researchers involve stakeholder groups. It's
9 simply a requirement and it's part and parcel of
10 how a project is put together.
11 As Dr. Forsythe was talking about, PCORI
12 also expects it. It's a piece of it. And as more
13 and more pragmatic clinical trials are being
14 conducted and reported, stakeholder involvement is
15 generally expected to be a big part of the
16 pragmatic clinical trials as well. So we're going
17 to be seeing more and more and more of this because
18 it increases the rigor and impact of our clinical
19 research.
20 The third key issue is that all the methods
21 and procedures in a study need to be clearly
22 described so that readers can understand exactly

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1 what you did and can replicate it, if needed. When
 2 stakeholders play a role, that role must be
 3 described, as expected, in any paper. It needs to
 4 be clear, thorough, and brief.

5 In thinking about this, I think about the
 6 person who's looking for a small house with big
 7 rooms, and lots of them. In any paper, we want to
 8 have it be very thorough and very clear, and we
 9 want it to be brief, and that's always the
 10 challenge, to make all that work. But you read
 11 paper after paper in our journals, and you see that
 12 it's successful.

13 As a tip, there are no word limits in the
 14 methods sections, both in the Journal of Pain and,
 15 as Frank may talk about, in Pain. So you have the
 16 room to discuss exactly what you did because the
 17 methods, and being able to understand what you did,
 18 and be able to replicate it is so important. But
 19 please don't take advantage. Don't just go on, and
 20 on, and on. Really think about how you can clearly
 21 describe what you did briefly, and remember that,
 22 certainly in the Journal of pain, many -- if not

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1 most, if not all -- journals now, allow for
 2 supplementary material and a wonderful place where
 3 you can describe in detail exactly what you did as
 4 the protocol.

5 Again, more and more sponsors are requiring
 6 that a protocol be completed, approved, in place,
 7 and dated prior to even enrolling subjects. If
 8 such a protocol exists, then you can make that
 9 available to your readers, and that's where you
 10 could describe more details about your procedures
 11 for stakeholder engagement. So those are the key
 12 points that I wanted to make.

13 DR. KERNS: Thank you, Mark. Perfect.

14 We're going to next hear from Dr. Frank
 15 Keefe. He's editor-in-chief of Pain. He's a
 16 professor in psychiatry and behavioral sciences,
 17 psychology and neuroscience, anesthesiology and
 18 medicine at the Duke University School of Medicine
 19 in Durham, North Carolina.

20 Frank, please, take it away.

21 Presentation – Frank Keefe

22 DR. KEEFE: Thanks, Bob, and thanks to all

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1 for the opportunity to participate in today's
 2 session.

3 Publishing really matters, and reporting
 4 what you do really matters. You may have done some
 5 wonderful things, and a lot of those have been
 6 outlined today, and I'm sure on previous days, to
 7 facilitate stakeholder or patient involvement. But
 8 unless that is written and gets published, it's not
 9 likely to have the impact that it might otherwise
 10 have.

11 So reporting on this is an extremely
 12 important topic, and I want to echo a comment that
 13 Laura made of how perspective really matters. I
 14 think that many of us have hold of this elephant,
 15 and we have different parts of the elephant. You
 16 probably all remember the story of the blind man
 17 and the elephant with various blind men handling
 18 different parts of the elephant, and claiming they
 19 knew exactly what the elephant felt like or is.

20 "It's like a hose," said the guy with the
 21 nose. "Oh, no; it's like a wall," and so on.

22 Fortunately, one of these wise men was very blind

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1 and he said, "Let's listen to each other. If we
 2 put our thoughts together, we're really going to
 3 understand what this looks like."

4 I think these types of meetings that you're
 5 having here are so important because it allows us
 6 to listen and talk to each other. And I'm
 7 impressed by the consensus of what should be
 8 happening in this field.

9 What I want to talk about, though, as an
 10 editor is, what do we see? What is actually
 11 happening in the world of publication, particularly
 12 with regard to pain and reporting of stakeholder
 13 involvement?

14 What we typically see in pain for clinical
 15 trials is randomized-controlled trials reporting
 16 the main trial outcomes. That's what comes into
 17 us. In fact, many people consider publishing these
 18 types of reports to be the primary paper that comes
 19 out of a clinical trial.

20 When those come in, they go out to review
 21 for reviewers who are experts in randomized
 22 clinical trials and various issues regarding the

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1 intervention and so on. What those reviewers are
 2 typically focused on are things like, was the study
 3 pre-registered? Were there multiple study sites?
 4 What was the control comparison? How about the
 5 evaluations that were used? And so on and so
 6 forth. They get very, very focused on this. And
 7 if they happen to be a really informed reviewer,
 8 they might be looking for evidence in each of these
 9 areas; has there been key stakeholder involvement?
 10 Some of the concerns, though, that reviewers
 11 will bring up, who have that perspective is -- and
 12 I think Mark alluded to this -- was there a
 13 description, even a brief description, of how
 14 stakeholders were involved? Was that description
 15 clear? Did the authors build a case at some
 16 point -- maybe in their introduction -- of why
 17 stakeholder involvement was important? How is the
 18 involvement accomplished? How much of an impact
 19 did it have and can it be replicated? If somebody
 20 tried to do the study again with a different group
 21 of stakeholders, having input across the study
 22 design, would it look similar or would there be a

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1 different outcome?
 2 The point I want to emphasize -- and this is
 3 particularly true of many prestigious, high-impact
 4 journals -- is, the problem is you're trying to
 5 cram an awful lot into that outcome paper. Mark
 6 mentioned the methods section. And you do have
 7 room there, but probably not the room to really
 8 show, if you were very committed to stakeholder
 9 involvement, the sophistication and breadth of
 10 things that you did to really improve your study.
 11 People really feel kind of crammed for
 12 opportunities. I think one of the key issues here
 13 to keep in mind from a publication perspective is
 14 that, traditionally, this is what investigators
 15 often get focused in. "I want to get the primary
 16 outcome paper. I want to get it in the New England
 17 Journal, or JAMA," or wherever it might be. And
 18 they're so focused on this when they think about
 19 stakeholder involvement and, "How do I possibly
 20 convey the sophistication that I attempted to use
 21 in pulling this together and getting stakeholders
 22 involved in that primary outcome paper?" It's

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1 hard. It really is hard.
 2 However, if you take a somewhat different
 3 approach, that is one that views this primary
 4 outcome paper as one of the suite of papers that
 5 could be used to highlight the role of stakeholder
 6 involvement, then I think you have a much more
 7 balanced approach.
 8 You could write a review paper, building the
 9 case for not only the study but why stakeholder
 10 involvement was so important; a protocol paper
 11 where you describe how the stakeholders, the
 12 patients, actually influence the way the study got
 13 put together. If your study involves particularly
 14 a behavioral intervention, you might want to have a
 15 paper that describes the intervention technique.
 16 You might want to have a manual and highlight the
 17 parts that feature stakeholder involvement, and so
 18 on and so forth.
 19 The point is that there are a variety of
 20 routes. There are a variety of avenues to
 21 highlight stakeholder involvement and to publish
 22 reports of that stakeholder involvement. Clearly,

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1 the primary report is important, but I think that,
 2 typically, the limitations of all the other things
 3 that you want to address in detail permit, really,
 4 displaying the sophistication and the rigor with
 5 which you may have approached stakeholder input
 6 into your study.
 7 I think that's my last slide. Yes.
 8 Clarifying Q&A
 9 DR. KERNS: Beautiful. Thank you very much,
 10 Frank.
 11 Any clarifying questions for either Mark or
 12 Frank?
 13 Chris, go ahead.
 14 MS. VEASLEY: Yes. Thank you for those
 15 talks; very informative. Some of the investigators
 16 involved in this meeting, and others that we've
 17 heard from, have been discouraged by the fact that
 18 some of their publications were asked to be
 19 revised, or flat-out rejected, when they go into
 20 detail about stakeholder involvement in their
 21 clinical research.
 22 I guess my kind of provocative question to

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1 you, Frank and Mark, is why should an investigator
 2 have to make a case for why stakeholder engagement
 3 should be included in their publication? I would
 4 think that it would actually be the opposite, that
 5 if they didn't, they need to make a case for why it
 6 was so.

7 And I'm not talking about all types of
 8 research -- cross, basic, and whatever -- but
 9 particularly clinical pain research, particularly
 10 since funding agencies are now requiring this to be
 11 a part of clinical research when it's included in
 12 funding announcements and other areas.

13 DR. KEEFE: Well, you know, Chris, this is a
 14 process, and I think this meeting is part of that
 15 process of educating people in the field of what is
 16 needed, particularly with regard to stakeholder
 17 involvement.

18 In defense of the people looking at this
 19 work, reviewers and so on, they have been educated
 20 about a myriad of things that are important. We
 21 could go through all the different criteria for
 22 clinical trials. There's a myriad of things that

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1 they need to focus on. And stakeholder involvement
 2 may be there, but it's not emphasized as much as
 3 some of the things they typically look at.

4 I think the way to move the needle is to
 5 educate people, to raise the status of this. That
 6 being said, I don't think any one publication --
 7 for example, the primary outcome paper -- is the
 8 only way to highlight what has been done or
 9 necessarily the best way. So when you talk about
 10 people being asked to change, I would ask what
 11 papers. Was that a chapter in a book where they
 12 were talking about this? Was it a paper where they
 13 described the conceptual model that guides their
 14 research, and so on so forth?

15 So, to me, it depends a lot on the type of
 16 submission as well. But reviewers need to be
 17 educated, and I'm really glad that I was invited to
 18 this panel because I think also members of
 19 editorial boards need to be enlightened and
 20 educated about the importance of this.

21 DR. KERNS: Thank you, Frank.
 22 Mark, do you care to add anything?

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1 DR. JENSEN: Yes. I'll just reiterate that
 2 I agree with Chris. Again, if stakeholder
 3 involvement was part of the study, it must be
 4 included. You don't have to make an argument for
 5 why; it must be included. The issue more is what
 6 Frank and I both alluded to, is how and where. And
 7 it certainly should not be left out of the primary
 8 people, at least a paragraph. And if you want to
 9 go in great detail, that's fine, but maybe for
 10 supplementary material for that. So put it in
 11 there, would be my point.

12 DR. KERNS: I heard also something I want to
 13 emphasize, I guess, in Frank's comment, is that
 14 this is a process. I heard a little bit about
 15 congratulations or a compliment for holding this
 16 meeting, and I think it's a good opportunity.

17 I thank Bob and Dennis and ACTTION and
 18 IMPACT for supporting this because we're hopeful
 19 that, like so much else that come out of these
 20 IMPACT conferences, this, too, will have an
 21 impact, and maybe not just moving the needle a
 22 little bit, but actually stimulating much needed

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1 action in the clinical pain research community.

2 Bob Dworkin, you have your hand up, and then
 3 I'll call on John. And I do have a plan to
 4 actually call on a couple people who had their
 5 hands up earlier for other points to give other
 6 people a chance. Then we'll hand things over to
 7 Simon, who will lead our broader discussion moving
 8 forward.

9 So, Bob?

10 DR. DWORKIN: Thanks, Bob, and thanks for
 11 the nice comments.

12 I think this is a question for either Mark
 13 or Frank. Of course, both of your journals will
 14 require authors to do certain things: disclose
 15 conflicts of interest; include a consort diagram;
 16 et cetera, et cetera.

17 Should you also require that in clinical
 18 pain research there be a statement of whether or
 19 not patients were involved, engaged, in any way?
 20 And if that attestation, if you will, is that
 21 patients were engaged, there be a brief description
 22 of the nature of the engagement? I don't think

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1 either of the journals require that kind of patient
2 engagement statement, and could that be something
3 that you could include?
4 DR. JENSEN: I'll just jump in. You know,
5 whether or not a stakeholder involvement is
6 necessary depends on the goal of the study. There
7 are certainly highly rigorous studies in which it's
8 not necessary and there are studies in which it is
9 important.
10 As I'm thinking about this right now in
11 response, I don't know that you'd need to have a
12 statement that says we didn't do it in this case,
13 and this is the reason, because I think it should
14 be clear; if you did it, describe it. What you did
15 should be clearly described.
16 So there's, in my view, a general -- if we
17 had an attestation, we'd want to have an
18 attestation of describe what you did. But I think
19 that's there already, so we can discuss it. But it
20 doesn't strike me right now that such an
21 attestation should be necessarily required.
22 DR. DWORKIN: Well, I just have to jump in,

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1 Mark, and we can take this offline. I would love
2 to hear examples from you of studies, clinical
3 research in pain, where there would be no potential
4 benefit whatsoever of involving patients, because
5 you were suggesting that there are such studies.
6 Even, it seems to me, if you convince me
7 that there are such studies, why wouldn't the
8 author add a sentence to the manuscript, saying,
9 "We did not include any patient engagement in this
10 research for the following reason"? I would love
11 to read statements like that. It would be very
12 educational and informative.
13 DR. KERNS: Christine Chambers had a comment
14 in the chat saying, "I wonder what patients'
15 perspectives would be on this issue."
16 John Farrar?
17 DR. FARRAR: Yes. Thanks for excellent
18 talks, both of you. One thing struck me
19 particularly, Frank, that you said and that I'd
20 like to build on, which is that you need to defend
21 in any paper of any randomized trial why you chose
22 a particular outcome, how you chose a particular

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1 population, and in what way did you decide to do
2 the research? It seems to me that maybe we're
3 drawing a line where there isn't one.
4 The patients play an important role in the
5 design, the conduct, and the management of trials
6 as they go along, the same as any of the other
7 researchers involved in that process. So if I am
8 reviewing a randomized trial, I would look at the
9 outcome and the reason for choosing that outcome,
10 and a comment that said, "Our patients are members
11 of the committee and strongly encourage the use of
12 this one versus that one because it was more
13 applicable to their patient populations," who have
14 a very strong justification for why that was
15 chosen.
16 So I think maybe we're doing ourselves a
17 disfavor by trying to say it's something special
18 and different. It seems to me that including
19 patients as part of the research team is just a
20 natural outcome of trying to make our research
21 impactful, and I wonder what your thoughts are, or
22 Mark's thoughts are, on thinking about it from that

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1 perspective of how choices get made.
2 DR. KEEFE: I think all the publications
3 relevant to any program of research should
4 highlight this. I think the idea that Bob had is
5 an intriguing one, and it's one that we'll take up
6 at our editorial board meeting, where we're
7 constantly updating our policies for open science
8 and transparency. I think it's a very interesting
9 idea.
10 But it doesn't just refer to one aspect of
11 the program of research. I think the point you're
12 bringing up is there are a lot of very
13 sophisticated decision-making processes that go on
14 across a trial --
15 DR. FARRAR: Yes.
16 DR. KEEFE: -- and I think they all provide
17 opportunities for stakeholder involvement, and I
18 think across a range of publications on a research
19 program, the investigator should do all that they
20 can to emphasize that involvement, the role it
21 played, and how it shaped things.
22 DR. KERNS: I'm just aware of a busy chat,

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1 and I'm going to, actually, I think call on
 2 Christine Chambers to make her point that seemed to
 3 lead to other's comments.
 4 By the way, I'd also note as to this
 5 specific question about requiring patient
 6 engagement -- I did read it in detail -- that Laura
 7 Forsythe put in the chat a link to BMJ's statement
 8 about this that seems to maybe strongly encourage
 9 maybe it's even a little more than that, so please
 10 take a look at that.
 11 So Christine?
 12 DR. CHAMBERS: Yes, thanks. There are so
 13 many interesting pieces to react to here. I had
 14 just posted on the chat I'd be really curious to
 15 hear what some of that patient partners engaged in
 16 the meeting would think on this. But I think
 17 there's enormous opportunity, from an editorial
 18 perspective, to look at different interests; not
 19 just being focused on whether patients are engaged
 20 in the research that happened, but also in how
 21 patients can be engaged in review and editorial
 22 processes.

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1 I also think, for me, it's less about making
 2 sure the authors report what they did, which is a
 3 hundred percent critical -- that's just part of
 4 preparing a good paper and making sure you have
 5 that rationale -- but also the responsibility or
 6 the opportunity that the journals have in helping
 7 to shape quality patient engagement.
 8 When I think about the requirements that
 9 have evolved over the years with regards to
 10 conducting systematic review, or trials, and the
 11 expectations on reporting at the journal
 12 submission, I think there's a real opportunity to
 13 make sure that the journals are signaling
 14 downwards, that this is how we think quality
 15 patient engagement could be approached in science.
 16 I will say, as someone who submits often
 17 with patient co-authors, that I've had very
 18 negative experiences on the journal side. Just
 19 even the requirement that an institution be listed
 20 for every co-author, for example, has been a
 21 major-major challenge. I'm like, "This patient
 22 partner doesn't have an institution." But it's

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1 become a barrier to even submitting the papers. We
 2 often get into a lot of back and forth at the
 3 copy-editing phase about we must have an
 4 institution for this author, and I'm like, "There
 5 is none."
 6 So I think we need to think about where are
 7 the barriers within the system that you need to
 8 facilitate. I am not afraid, as you can tell from
 9 some of my provocative comments in the chat over
 10 the last couple of days -- I'm not afraid to be a
 11 bit disruptive, and I'm not afraid to take those
 12 risks, but a lot of really career researchers are.
 13 That's not the kind of conversation they want to be
 14 having with U.S. journal editors or with the
 15 publishing side of things. A lot of patient
 16 partners get turned off of the engagement and don't
 17 want to participate in the future.
 18 I will just say on the publishing piece, and
 19 then I'll shut up, that one of the things that I've
 20 learned about engaging with patient partners is the
 21 way that we engage as academics. Even our use of
 22 email, particularly when I'm engaging with

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1 youth -- I don't know if any of you have kids who
 2 are teenagers, but I have to text my kids to tell
 3 them to check an email because they don't use
 4 email. But a number of patient partners don't use
 5 email, and our whole journal publishing system is
 6 very automated and all based on email.
 7 So I think we need to really think about how
 8 we make things more accessible and how we can
 9 embrace different levels of contribution. I know I
 10 had inserted Isabel Jordan and her son in a Lancet
 11 commission that was led by Chris Eccleston, and we
 12 had lots of conversations about should there be
 13 authors on the paper; how will the Lancet manage
 14 this? So there are a lot of considerations, but I
 15 think we need to be a little bit flexible and a
 16 little bit disruptive around our typical processes.
 17 So I've thrown a lot at you there, but those
 18 are some of my thoughts.
 19 DR. KERNS: Well, thank you very much.
 20 There are a couple of new hands up, but I am
 21 going to take the liberty, before I turn the mic
 22 over to Simon, to backtrack a little. And I will

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1 get to the people that have their hands up now, but
 2 I want to start back with a few hands up that we
 3 didn't get to hear from earlier.
 4 I noticed Isabel Jordan has made a few other
 5 comments in the chat. So, Isabel, you have the mic
 6 now if you'd like to make a comment or ask your
 7 question.
 8 MS. JORDAN: Thanks very much, Bob.
 9 I'm actually going in the way-back machine
 10 to when David was talking about industry, and I was
 11 really gratified to see how they were putting in
 12 supports for folks in their company to have
 13 standards around and tools about how to engage with
 14 their patient partners. I think he called it a
 15 self-serve model so that they could go and have a
 16 standard way, really a common way, of interacting
 17 with patient partners.
 18 I think that's really important so people
 19 know what they expect when they're interacting with
 20 an organization, or a lab, or an industry, or
 21 whoever. And I was further gratified to see that
 22 they're doing this across industry and sharing

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1 tools. I think that's so important to create tools
 2 for folks doing the engagement work, but I think
 3 it's equally important to understand that patient
 4 partners need supports as well so that we can
 5 support one another.
 6 I'm curious whether he or his colleagues
 7 have given any thoughts to providing a similar kind
 8 of platform for the folks that they work with in
 9 the patient partner world to connect with one
 10 another so that they can connect over how their
 11 experiences are going as patient partners and to
 12 have that kind of shared experience together.
 13 Because I think that kind of platform for them to
 14 connect would also be really important to create
 15 that shared experience and shared knowledge about
 16 how to do work well.
 17 DR. KERNS: Thank you, Isabel. I should
 18 have realized this, that you're hemming up around
 19 David's presentation. He's not with us right now,
 20 but he said he was coming back. But I think the
 21 point is still very important. It underscored a
 22 couple key points, I think, that we're all hearing,

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1 and I'm sure Simon has captured that. And maybe
 2 there will be an opportunity later to raise it
 3 again when David is present.
 4 MS. VEASLEY: Bob?
 5 DR. KERNS: Yes, please.
 6 MS. VEASLEY: If I can just weigh in really
 7 quickly. Isabel, in our conversations preparing
 8 for the meeting, although he didn't include it in
 9 his slides, that's exactly what Pfizer's done.
 10 They've created kind of an online virtual community
 11 for people who have participated in that way
 12 throughout their entire research continuum, and
 13 also to basically advocate and help each other
 14 become advocates, because not everybody has that
 15 experience of what it means to be an advocate and
 16 how to do it well, and educating yourself.
 17 So maybe he can speak on it a little bit
 18 more, but they have done that.
 19 DR. KERNS: Thank you, Chris.
 20 I think next on my list from an earlier
 21 presentation was Sean Mackey.
 22 Sean, are you on, and would you like to make

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1 your couple comments, or question?
 2 DR. MACKEY: Yes. Thanks, Bob. This was
 3 related to the earlier discussion around industry,
 4 but I think it is a broader discussion as well, and
 5 it has to do with how to manage tensions.
 6 By way of example, we're involved with an
 7 FDA grant right now to develop a tool around
 8 decision-making related to how patients choose
 9 between medical devices that may help reduce their
 10 pain and may also help reduce opioids. This
 11 involves something called the Discrete Choice
 12 Experiment, and they have to choose different
 13 scenarios. We have to choose outcome measures for
 14 this, and we're fortunate to have patient advocates
 15 that have been involved from day one on the design
 16 aspect, two of which are on this call.
 17 It's wonderful when everything in the
 18 discussions go well, but I guess my question is,
 19 how do we handle tensions when there's
 20 disagreement? What I mean by that is there's going
 21 to be disagreement in at least a couple scenarios.
 22 One is what happens when the researchers simply

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1 disagree with the patient advocates over what
 2 should be measured and what they think is
 3 important?
 4 Then there's a second one, which I think is
 5 at least as important, which is, what happens when
 6 you agree with the patient advocates that they come
 7 up with something that they think is very important
 8 to measure, but it's not in line with the
 9 regulatory interests and the outcome measures that,
 10 for instance, the FDA is interested in measuring,
 11 and you simply can't do it?
 12 Now, we're fortunate to have a couple of the
 13 people, Penney and Chris, who are on here, who are
 14 two of the most grounded people you'll ever meet in
 15 your life. So we were able to work through those
 16 those tensions and have some really good
 17 discussions. But how have people handled this when
 18 there are tensions and disagreements? So I just
 19 put that out to the group.
 20 DR. KERNS: Thank you, Sean, for that
 21 important comment.
 22 I think Chris, the planning group, others,

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1 this is really an important issue. My own
 2 reflections on this is it's maybe not even fair to
 3 call it tensions, because -- if we all assume --
 4 people with lived experience or patients come from
 5 all different perspectives. They're not a uniform
 6 group. There's a huge diversity.
 7 Especially as we promote efforts to enhance
 8 the diversity of participation, the participants in
 9 these processes, we might expect to see more frank
 10 disagreements. Your issue about, ultimately,
 11 recommendations that emerge are discordant with,
 12 for example, regulatory requirements, that's a key
 13 challenge.
 14 I think we can take a couple of comments now
 15 around that if anybody would like, but I frankly
 16 think that this is a key question for the broader
 17 discussion later.
 18 DR. MACKEY: Well, I agree with you --
 19 DR. KERNS: There probably are some specific
 20 examples, and I think Laura Forsythe put something
 21 in the chat about what PCORI recommends or is a
 22 concrete strategy. I didn't have time to look at

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1 it.
 2 DR. MACKEY: I brought this up just because
 3 everything is wonderful when everybody's in
 4 agreement; you know, Kumbaya, and we all love those
 5 situations. But I think we would all benefit from
 6 learning how do we handle situations when there's
 7 just frank disagreement or these tensions, and how
 8 to navigate that I think is just of incredible
 9 importance.
 10 DR. KERNS: Yes. Thank you.
 11 Laura, you want to make a comment?
 12 DR. FORSYTHE: Sure. I was just saying,
 13 Bob, PCORI actually has, literally underway right
 14 now, a case study project about this exact issue.
 15 We had a couple years ago a qualitative interview
 16 project with investigators and partners, and then
 17 we did a follow-up, in-depth case study with six
 18 projects. Our specific research question there was
 19 how do people deal with tensions? And that was the
 20 word that we brought to the project.
 21 I just wanted to share, we literally were
 22 just looking through the analysis a couple weeks

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1 ago, so it's not out yet. But I can share, first
 2 of all, universally, the six studies, the
 3 investigators and the partners told us they shied
 4 away from that word "tension" and "conflict." They
 5 talked about difference of perspective or thinking
 6 through different ideas.
 7 I think a key element that came through was
 8 some of the projects were very intentional from the
 9 start, laying out their decision framework;
 10 decision rights; how they approach framework; how
 11 they were going to deal with difference of
 12 perspective; treating it not as a problem but an
 13 opportunity, and coming in when you build that
 14 foundation of here's how we're going to work
 15 together and here are our roles.
 16 Being true collaborators doesn't mean we can
 17 do everything that anybody wants, but being part of
 18 that foundation and also talking through what are
 19 the rigid bounds and what are the flexible ones;
 20 like where are there things -- just the scientific
 21 rules, the funder rules, the regulator rules,
 22 whatever -- that will not allow this. How else

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1 outside of this project, then, can we address that
 2 issue, and where are there more flexible bounds,
 3 where its history, or tradition, or preference that
 4 people might be able to think differently about?
 5 I will just also give a nod to a lot of our
 6 work in how to do engagement well meets the need
 7 for investigators or whomever and is really leading
 8 these conversations to develop their facilitation
 9 skills. We talk a lot about training for partners,
 10 but at PCORI we're also trying to talk a lot about
 11 training for researchers, or the team leads, or
 12 people because there really is an art to
 13 navigating. Difference of opinion is not specific
 14 to having patients at the table. There's
 15 difference of opinion among well-trained
 16 researchers as well, so it's the same strategies of
 17 how to navigate those.
 18 DR. KERNS: Thank you very much.
 19 I'm going to ask for some advice of Chris
 20 and Bob and Dennis. I'd like to continue this
 21 discussion for a minute. Well, it may go on for a
 22 few more minutes. There are several people now

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1 with hands up that want to make comments. But I
 2 also am aware of our plans and move toward turning
 3 things over to Simon.
 4 Do you think it's ok to go ahead with a
 5 little more discussion on this point?
 6 DR. DWORKIN: Sure, but maybe my two-cents
 7 worth would be to turn it over to Simon at 1:10,
 8 because we really want to make sure he has enough
 9 time to discuss the manuscript that he's going to
 10 be leading.
 11 DR. KERNS: Yes.
 12 Alright. So I'll call on several people in
 13 quick succession and try to wrap up by 10:10; I
 14 mean 10 after the hour. I'm going to call on
 15 Isabel Jordan or Christine Chambers, who had
 16 comments, and then Lee Simon, and then go back to
 17 my list.
 18 MS. JORDAN: I think one of the fundamental
 19 tensions that people feel is that when you're
 20 bringing in patient partners to do work, especially
 21 if it's new for you, fundamentally, we're coming
 22 from often a very different perspective, especially

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1 if you're bringing people in that don't come from
 2 an academic background or a background that
 3 involves coming from a post-secondary institution.
 4 And that can be fundamentally uncomfortable because
 5 you might hear things that you haven't heard before
 6 and opinions that feel very discordant to your own.
 7 And that's fundamentally uncomfortable, and that's
 8 ok. It's ok to be uncomfortable, and it's ok to
 9 have awkward conversations.
 10 I really echo the previous comments that
 11 increasing your facilitation skills is really
 12 important. But I think one of the most practical
 13 tips to have, and I think one of the things that
 14 has, from a personal point of view, made me most
 15 comfortable is if from the beginning there's
 16 clarity really made around whose role is in charge
 17 of what.
 18 So what are you actually asking the patient
 19 partner to do? What do you want them to chime in
 20 on and what don't you want them to chime in on?
 21 What is the actual purview of this project or this
 22 clinical trial that they can have some agency

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1 around so that they don't go down the road thinking
 2 that they have agency over something when they
 3 don't?
 4 The parts that you really have said that you
 5 want them to have some agency over, you listen to
 6 them, and you take in their opinions, and that they
 7 know where the limitations are from a regulatory
 8 point of view that you have no control over, and
 9 those continuing clarifying conversations that may
 10 be uncomfortable kind of keep happening.
 11 That tension around not agreeing over things
 12 is ok as long as you keep having those clarifying
 13 conversations. I don't expect to have birthday
 14 cake every day, even though I would really like to.
 15 Nobody wants everything to go their way all the
 16 time. They understand they're working within the
 17 team. But you don't want the bait and switch
 18 either, where you think that you have control over
 19 something because it's not made clear, and then you
 20 don't. So that's my two cents of advice.
 21 DR. KERNS: Alright. I noticed Christine
 22 basically was giving the handoff to Isabel, and

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1 she's been mostly shaking her head and smiling as
 2 Isabel was -- so I don't think I need to call on
 3 her.
 4 I'm going to actually call on Lee Simon, who
 5 put something in the chat about OMERACT. Would you
 6 like to make your comment, Lee?
 7 DR. SIMON: Yes. Thanks, Bob.
 8 We work in OMERACT as if there is literally
 9 no difference between our patient research partners
 10 and our investigators and other individuals who are
 11 stakeholders, and we often have regulatory people
 12 within our discussions.
 13 One perfect example was when we were
 14 developing the criteria for measurement of domains
 15 of flare of rheumatoid arthritis, and pain is a
 16 very important part of that. But there was a big
 17 debate about fatigue and how much fatigue plays a
 18 role; and how much of it is driven by pain and all
 19 the various different components; and whether or
 20 not that would be 1 of 7 things to measure; and how
 21 would you measure fatigue.
 22 Interestingly enough, this actually evolved

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1 into a rather closed meeting at the FDA between the
 2 review divisions, the senior leadership, OMERACT,
 3 and patients as they were discussing the issue of
 4 fatigue because the critical path was developing an
 5 actual format and approach to fatigue.
 6 The way it actually got resolved over some
 7 time -- maybe even six months -- was recurrent
 8 delphi of a larger group of people that were not
 9 necessarily only those involved in the discussions
 10 at the table; that in fact it then led to a real
 11 congruency of thinking regarding what we were
 12 trying to achieve.
 13 I think that the reality is you have to
 14 assume, and everybody has to assume, that
 15 everybody's equal around that table. In my field,
 16 physicians believe that they're the ones that are
 17 the adjudicators and can know how a patient
 18 responds. What I've learned, both by being a
 19 regulator and clinical investigator, is, in fact,
 20 it's the patient who knows what's going on. We
 21 think we observe what's going on, but as
 22 physicians, we really cannot understand entirely.

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1 So I would urge anyone that has that kind of
 2 conflict that Mark has brought up, which is real
 3 and can happen, is that, fundamentally, you work it
 4 out. You continue to talk, you continue to debate,
 5 and you go to a larger audience and decide on how
 6 they think about that and how to do that. So
 7 that's what I want to point out.
 8 DR. KERNS: Thank you, Lee, very much.
 9 We have just a couple more minutes, and
 10 there's a lot going on in the chat. Because Lynn
 11 Laidlaw doesn't have the capacity to speak orally,
 12 could I ask Chris, would you prepare a quick
 13 summary of what Lynn has said, to speak orally, in
 14 just a minute?
 15 Let me, in the meantime, call on Kathryn
 16 Martin, who's been very patient, to make your
 17 comment, and then I'll close out this by asking
 18 Penney Cowan to make a comment. Then I noticed
 19 Kristin Carman's hand just came up, but I think
 20 after the first two comments, we'll have to go to
 21 Simon.
 22 So, Kathryn?

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1 DR. MARTIN: Yes. Sure. I just wanted to
 2 say that Lynn and I actually have been part of a
 3 team supervising two medical students undertaking a
 4 review, looking at and trying to evaluate the
 5 reporting of patient partner involvement in chronic
 6 pain research. Very interestingly, part of that
 7 conversation around how is that being reported in
 8 the literature and the role of the editors and
 9 journals for this is quite interesting.
 10 The few number of papers that we've been
 11 able to identify that do it well, and the areas in
 12 which they bring this into their manuscripts and
 13 where things are actually highlighted, we were even
 14 looking at getting things like patient partners
 15 being included as authors and whether they had been
 16 acknowledged.
 17 It's still being worked on at the moment,
 18 but I do want to say that we have been looking to
 19 see how -- because the focus was how patient
 20 partner involvement has been involved across all
 21 the different life cycles of research. So yes,
 22 it's quite interesting, actually.

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1 So I do think that there is hope to try and
 2 improve that in terms of reporting, whether or not
 3 that's through some of the reporting tools like
 4 CAS [ph] and other stroke [indiscernible]
 5 guidelines, et cetera, trying to make sure that
 6 patient partner involvement is noted there. That
 7 could be another avenue as well.
 8 DR. KERNS: Thank you very much.
 9 It is 1:10, but I'm going to ask Penney to
 10 make a brief comment, and then I'll turn things
 11 over to Simon.
 12 MS. COWAN: I think one of the problems is
 13 that -- and someone said this earlier -- we're
 14 representing our own opinion, and we can't speak
 15 for everyone else. So when we have those kind of
 16 opinions, it's our word, so it may not be
 17 taken -- I always feel like we need to ask
 18 [inaudible -- audio gap] -- goes down to whether
 19 surveys or focus groups -- [inaudible], and those
 20 that are underreached, as we heard before, and ask
 21 them to chime in, and then let's take that back
 22 along with the opinions.

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1 So it just gives more validation, which I
 2 think all people are looking for that validation.
 3 So it might be better to get a broader view if
 4 there is that disagreement on what do others think.
 5 I know, Sean, we did do one [inaudible] on
 6 some of those issues because we wanted to
 7 know -- it wasn't on this particular one, but I
 8 think that's something that he had delved into, and
 9 I think it's important [inaudible] both, focus
 10 groups, but also surveys. The problem with a lot
 11 of this is people who access all this information
 12 are not your average consumers because they have
 13 all the access, and like Chris said earlier,
 14 they're more educated people.
 15 So I think we have to actually go out on the
 16 ground; I mean, that's what I've always done. I
 17 always believe in the underdog, and let's go out
 18 and meet them where they live. Whether it's a VA
 19 or an Indian reservation, it doesn't matter; in a
 20 farming community. That's where we need to really
 21 start talking to people, and I think we've always
 22 missed that.

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1 DR. KERNS: So, thank you very much Penney.
 2 Thank you very much to our presenters today,
 3 and to this rich discussion. It's very clear to me
 4 that Simon has his hands full managing the chat and
 5 the dialogue that we're going to undertake now.
 6 It's just been great. But it also seems clear that
 7 we've kind of transitioned into a broader array of
 8 issues and just reacting to our panelists today.
 9 So again, thanks to the panelists, and at
 10 this point, I'm going to hand things over to Simon.
 11 Discussion and Development of
 12 Recommendations for Publication
 13 DR. HAROUTOUNIAN: Thanks so much, Bob.
 14 First of all, I tremendously enjoyed those
 15 last three days of conversations. I learned a lot.
 16 I have to admit that even though it might be a
 17 somewhat challenging test to try to incorporate all
 18 the comments and viewpoints in a recommendation
 19 manuscript, I'm really very excited for this
 20 opportunity to try to do it.
 21 I really wanted to start with presenting to
 22 you some thoughts on how we might want to structure

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1 this manuscript going forward. But I think as we
 2 would do around the table when we have different
 3 partners -- for example, thinking about a design or
 4 clinical trial -- I really want this to be a
 5 discussion where everyone feels equal to contribute
 6 and to share ideas, and thoughts, and criticize
 7 things that might not look appropriate.
 8 So I will take the liberty to present some
 9 initial thoughts about the management structure and
 10 highlight some key points where we might want to
 11 have a discussion and some clarifications. But
 12 then I think we'll have ample time to allow both
 13 for specific comments about the manuscript, but
 14 also some thoughts about previous presentations,
 15 where people didn't have a chance to share their
 16 views.
 17 The overall thought process about the
 18 proposed IMMPACT XXV manuscript, the initial idea
 19 was should patients be included as partners in
 20 trials of pain treatments? And I think based on
 21 the presentations that we heard in the past three
 22 days, the answer to the first question really

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1 seemed to be quite obvious; that there is really a
 2 strong rationale for including patients as partners
 3 in our clinical pain studies and trials, whether
 4 it's drugs, or device, or anything else.
 5 I think one of the key points that we'll
 6 need to present as a part of this manuscript is
 7 really try to highlight some of the key benefits
 8 that are related to including patients as partners.
 9 I think we had several very important and thorough
 10 presentations of what would those benefits be,
 11 whether it's related to retention and recruitment
 12 for patients or whether it's related to the fact
 13 that the studies are going to be more clinically
 14 relevant, and I have some of those details on the
 15 next slide.
 16 One of the thoughts was, actually, as we're
 17 going to present this to the readers, also be
 18 transparent about what might be the costs
 19 associated with engaging patients as partners in
 20 the continuum of the clinical trial design and
 21 conduct. And I'm not talking just specifically
 22 about monetary costs, but also indirect costs that

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1 several of the studies or several of the
 2 manuscripts have highlighted.
 3 One of the ways I would propose for us to
 4 think about the benefits and the costs is rather to
 5 present this as value. So what is the value of
 6 having patients engaged as partners in clinical
 7 trials, and really thinking whether those benefits
 8 outweigh the potential costs, and what are the
 9 different issues associated with those costs, and
 10 whether there are ways to overcome them.
 11 I think, based on that initial presentation,
 12 the idea would be to describe if we're going to
 13 include and involve patients as partners in our
 14 clinical research and how to do this well. I think
 15 we have heard several presentations about what are
 16 the different components that need to be considered
 17 and what are the different lessons that we have
 18 learned from different areas -- and maybe not
 19 necessarily pain specific -- that we can maybe
 20 translate, adapt, or extrapolate it to come up with
 21 some certain recommendations about advice in
 22 clinical pain treatment studies.

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1 It would also be important to think about
 2 what were the different gaps that were identified
 3 in this process so we can both come with our best
 4 current recommendations for the field, but also
 5 highlight some of the key gaps and formulate
 6 potentially as future research agenda items. And
 7 maybe the manuscript that will result from this
 8 meeting would actually have some of those future
 9 agenda items where researchers, and regulators, and
 10 funders can perhaps take, as we would hope those
 11 items might have some kind of impact.
 12 So to initiate the discussion -- it's hard
 13 for me to monitor the chatbox, so Bob or Chris, if
 14 you could help me, perhaps, monitor it, and if
 15 there are any particular urgent comments, maybe to
 16 let me know -- one of the points that I thought
 17 would be useful to start with is some summary based
 18 on the initial presentations, but also the
 19 narrative review that was presented on day 1 of
 20 representative items that were collected about the
 21 perceived benefits that we might want to outline in
 22 our manuscript, and also some of those challenges

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1 and costs.
 2 Some of those items that can start this
 3 conversation, among the benefits that were
 4 presented in those three days, really are things
 5 that improve relevance of research to patients and
 6 patients priorities. In many different areas,
 7 there were points raised about the significant
 8 contribution to trial design. Lee Simon presented
 9 the issue of fatigue or thinking about the outcomes
 10 that really matter to patients; improve patient
 11 information materials and informed consent
 12 documents.
 13 We heard that language matters and we want
 14 to make this about the patients rather than other
 15 team members; improve both enrollment and
 16 retention, including decreased attrition from the
 17 studies, and really important points about improve
 18 dissemination, as well as further down the road,
 19 implementation of research findings, and
 20 potentially really increase public trust in the
 21 research process and outcomes, as patients are key
 22 partners in this process.

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1 Some of the key challenges that were raised
2 really are related to time as a cost component both
3 to researchers and patients and patient partners;
4 potentially increased cost; and the fear of
5 symbolism, or tokenism, or a checkbox issue,
6 including patients as partners in a non-meaningful
7 way.
8 I think, as Sean Mackey raised, the
9 component of what do we do if there are some
10 changes to research scope, for example, that are
11 not feasible in terms of regulators and how to
12 address some of those conflict resolution issues.
13 As well, I think one important point is that
14 oftentimes clinical researchers are not necessarily
15 trained in this component of engaging patients as
16 partners, and how do we address that lack of
17 resources and lack of training? I have another
18 slide at the end about the potential resources and
19 what the recommendations might be for funders.
20 So I would like to pause here and really
21 hear from the group, both in terms of the general
22 structure or the outline of the manuscript; whether

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1 this is something that sounds reasonable; whether
2 there's criticism; whether there are key components
3 that we can add; and also start the discussion with
4 outlining the perceived benefits, as well as costs,
5 or barriers, or limitations before we move forward.
6 I see a hand raised; Ian Gilron?
7 DR. GILRON: Yes. Thanks, Simon. Can you
8 hear me?
9 DR. HAROUTOUNIAN: Yes.
10 DR. GILRON: I think this is an excellent
11 way to organize things, and I really like it. I
12 don't know how to layer this onto it, but I wonder
13 if also we can add the different domains in which
14 patient partnership can occur. For example, very
15 literally and directly to help inform study design
16 and conduct versus patient partners being involved
17 in setting research priorities and getting involved
18 in research policy, to even another level of having
19 patient partners involved in governance of research
20 organizations and research networks.
21 Your rubric will be very useful, but it may
22 look different, depending on those different

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1 domains. So I'll just add that at this point.
2 DR. HAROUTOUNIAN: It's really good -- I do
3 have a slide, later, that thinks about how do we
4 present actually those costs, and values, and
5 opportunities from the different perspectives. How
6 can we consider the lens of, A, the researchers,
7 funders, patients, but also, as you said, in the
8 different settings?
9 In a phase 1 trial, things might look a
10 little bit different versus a phase 3 trial, and
11 how this manuscript can potentially address this
12 plethora of complex -- I definitely don't have an
13 answer, but I think it's an important point maybe
14 to hear from others on the call on what might be
15 the different ideas or ways of thinking about those
16 different reasons.
17 DR. GILRON: I just want to add one last
18 thing to that. In some discussions that I've had
19 with colleagues from basic science, it seems that
20 everyone at this meeting, we're sort of preaching
21 to the choir, and we're all in favor of this and
22 think it needs to move forward. But people in

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1 basic science, as one can imagine, can sometimes
2 have challenges in trying to demonstrate the
3 benefit tomorrow to the patient suffering from
4 pain, when we're trying to understand fundamental
5 mechanisms of nociception and how pain is
6 transmitted, and getting into nuances of neural
7 mechanisms.
8 So I think in terms of perceived threats of
9 patient engagement, I think there is something that
10 needs to be considered from the basic science
11 perspective, where it would be hard to articulate
12 short -- the obvious thing is identifying a new
13 molecule that's going to treat pain, but
14 understanding fundamental science of pain is hard
15 to demonstrate the benefit to a patient partner.
16 So that's another issue of perceived threats.
17 DR. HAROUTOUNIAN: That's a really good
18 point.
19 Chris?
20 MS. VEASLEY: Yes. I was just going to
21 say -- in response to Ian's comments, which are
22 really important -- I can envision maybe two tables

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1 or diagrams, one which is similar to what David
2 presented earlier today, which shows across the
3 research life cycle or continuum, all the way from
4 preclinical to phase 3 and phase 4 trials, the ways
5 in which patients/stakeholders can contribute to
6 different parts.

7 Obviously, the contribution at a preclinical
8 space is going to be different than versus a
9 phase 3 type of trial. Also, PCORI has some really
10 nice rubrics, and others as well, that present, as
11 you mentioned, all the different ways in which
12 patients can contribute, all the way from
13 unidirectional and focus groups surveys, all the
14 way through being co-PIs on a study and having
15 complete decision-making power on the grant. Those
16 kind of rubrics and figures already exist.

17 Would that address your concerns, Ian, in
18 terms of including those in the manuscript?
19 DR. GILRON: Yes. That's great.
20 DR. HAROUTOUNIAN: Yes, great comment,
21 Chris.
22 I see that Christine Chambers has her hand

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1 up.

2 DR. CHAMBERS: Thanks for organizing this so
3 nicely. I think it's fantastic. A couple of
4 reactions and, again, I'm not sure if this is the
5 place or not the place. But in particular,
6 thinking about Ian's comment just now, I think we
7 have an opportunity to shout out the importance of
8 engaging trainees and that training component.

9 I think the basic scientists that we've
10 trained through the North American Pain School, the
11 patient engagement component there has been highly
12 influential, and I think it has really influenced
13 their thoughts on this moving forward. But I
14 agree, when you have scientists who are more senior
15 or very used to doing things a certain way, that
16 can be a challenge. So I'm not sure where that
17 training piece and opportunities -- but I feel like
18 these manuscripts are so influential, so highly
19 read, so highly cited, a bit of a call-out to
20 training opportunities.

21 I also wanted to pick up on a point in the
22 chat. And Bob, I see your comment. I can tell

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1 it's stressing you out, that all this dialogue is
2 happening in the chat. And I think you just need
3 to embrace it as like a parallel stream of
4 engagement at the meeting, and we can download it
5 after, and you can keep a record of it.

6 But I think this is one of the things I've
7 learned, that some people and patient partners are
8 just maybe more comfortable pasting in the chat. I
9 think we have to acknowledge that sometimes we can
10 be a scary group, and that could inhibit
11 participation.

12 DR. KERNS: Christine, let me make a
13 comment. I entirely agree, except for one thing,
14 which is there are a few people that are on phone
15 only --

16 DR. CHAMBERS: Right.

17 DR. KERNS: -- and don't have the privilege
18 of seeing what's in the chat, which is why I
19 really -- I agree. It's not a black or white
20 thing, but I do want people to feel encouraged to
21 share orally if they're comfortable doing it.

22 DR. CHAMBERS: Sure. No, that's great. And

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1 sometimes with some of these meetings, they
2 actually download the transcript and share the
3 transcript from the Zoom chat after, so that people
4 can see what happened in the chat.

5 But I think this issue around the IRBs -- or
6 in Canada we call them research ethics boards -- is
7 really interesting. And I apologize if this came
8 up; I sometimes have a hard time fully attending
9 the Zoom meetings continuously. But this has been
10 a very significant barrier with my own research
11 ethics board not understanding patient partnership,
12 wanting me to create consent forms for the patient
13 partners who are collaborating on the project.

14 So I just wanted to flag that. I think
15 that's something important that I didn't hear
16 emphasized. And again, I apologize if I missed it.
17 But that has been a significant barrier, and I
18 think providing some commentary in the paper around
19 how to best navigate and some of the challenges
20 there might be helpful.

21 DR. HAROUTOUNIAN: Christine, thanks so much
22 for this important point.

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1 Can I unshared my slides as we're talking?
2 I think it creates a little bit better vision of
3 who is on the call, and we can at least see the
4 faces. And then if I need to share something, I'll
5 reshare them.
6 I don't think we really touched upon the IRB
7 at all. We might need to go back and see what is
8 out there in terms of published information and
9 data as an additional barrier, and maybe consider
10 that as another piece.
11 I see Jan Vollert has his hand up. Go
12 ahead, Jan.
13 (No response.)
14 DR. HAROUTOUNIAN: You're still on mute; the
15 sentence of the year, right?
16 (Laughter.)
17 DR. VOLLERT: I want to link into Ian's
18 comment and Chris' reaction to it, which I
19 completely agree on, and just want to echo it. We
20 may even think that along the pipeline, patient
21 engagement could almost be seen as a gradient,
22 getting more and more important and more and more

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1 impactful as close as we get to the clinic; so
2 starting with basic research, where we would say
3 patient involvement is important, but the scope and
4 impact might be way more limited than it is towards
5 the end in humans when we're going to clinic. And
6 that is almost like a triangle shape going from
7 basic discovery research into clinic.
8 DR. HAROUTOUNIAN: Yes. I agree. Thanks,
9 Jan.
10 Christine Goertz?
11 (No response.)
12 DR. HAROUTOUNIAN: We can't hear you,
13 unfortunately. You don't seem to be on mute,
14 but -- sorry. We'll come back to you.
15 I did want to come back to one of the
16 comments particularly about training. It is
17 important, and we actually did have a slide. So
18 while Christine is reconnecting, maybe I'll share
19 one of those slides that Chris presented earlier.
20 Some of this relates to maybe some advice or
21 recommendations towards funders, because I think
22 one of the issues that came up is that oftentimes

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1 we want to engage patients as partners as early as
2 possible in the planning stages of the studies,
3 rather than after the study has been funded, and
4 many of the institutions and organizations don't
5 have resources to potentially initiate that process
6 early on. This might be even more important for
7 communities with not a lot of resources or
8 developing countries, for example.
9 One of the potential outputs from this
10 meeting could be potential thoughts about what are
11 the recommendations for providing training at two
12 programs where there is clinical research, graduate
13 programs, et cetera, but also to the part of
14 initial, maybe, institutional resources for study
15 planning. And that's another point where I think
16 your input and some thoughts would be very helpful.
17 So maybe while people are thinking about
18 this, we can try to go back to Christine and see if
19 your microphone works.
20 DR. GOERTZ: Are you able to hear me now?
21 DR. HAROUTOUNIAN: Yes. Perfect.
22 DR. GOERTZ: Oh, great. Thank you.

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1 DR. HAROUTOUNIAN: And I'll stop sharing so
2 we can see each other.
3 DR. GOERTZ: Terrific.
4 A great discussion, and just getting back to
5 the issue of the IRB, which I think is really
6 critically important, it's not just the IRB. There
7 are so many ways in which the infrastructure upon
8 which we build our research is not focused to
9 consider patient engagement. From the IRB, all the
10 way through the discussion that we had earlier
11 about publications, I think that is a really
12 important barrier that we need to address.
13 I also would like to comment on the
14 discussion that we just had about basic science and
15 what impact can patient engagement have on the
16 continuum of research. And my question to all of us
17 is, who gets to decide that? I mean, who decides
18 whether patient engagement is important for a
19 particular project? In the same way that
20 investigators don't get to decide what is safe for
21 patients, should investigators get to decide
22 whether patient engagement is appropriate for a

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1 particular study? I just think it's something that
 2 we need to think about.
 3 Finally, Bob, earlier you had said that one
 4 of your hopes for this meeting, and my hope also,
 5 is that this can serve as a catalyst for really
 6 facilitating patient engagement in pain research.
 7 I think that that's incredibly important. But I
 8 wonder, that we are a group of mostly researchers
 9 with some patients who are already pretty
 10 sophisticated when it comes to participating in
 11 research, and I'm just wondering if there's an
 12 opportunity, when we get our key points put
 13 together, can we have some vehicle for getting
 14 public comment, broader public comment, and maybe
 15 including that as part of the manuscript, or
 16 including that as an addendum to the manuscript, so
 17 that we really make sure that we're not
 18 participating in some group think that is somehow
 19 missing really important points. Thank you.
 20 DR. HAROUTOUNIAN: This is fascinating and I
 21 think challenging -- no, not challenging, but I
 22 think it's a really interesting proposal. I don't

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1 remember that any of the IMMPACT manuscripts had
 2 this sort of mechanism of public comments.
 3 But, Bob, Dennis, maybe this is timely and
 4 interesting enough, and maybe in communication with
 5 journal editors something to think about, that if
 6 this is patient-focused output, do we actually want
 7 maybe broader representation of thoughts of
 8 patients on the product of this meeting?
 9 DR. DWORKIN: I'll respond to that. There
 10 are, of course, preprint kind of websites for
 11 manuscripts; MetaArchive, et cetera. I actually
 12 don't know the policies of Journal of Pain and Pain
 13 with respect to putting a manuscript on one of
 14 those sites.
 15 DR. JENSEN: You can do it.
 16 DR. DWORKIN: Okay. That would be a way to
 17 solicit public input that could then be included as
 18 an electronics supplement when the manuscript
 19 finally gets submitted to Journal of Pain or Pain.
 20 So it's certainly something that we could do.
 21 We've never done that before. It's kind of cool,
 22 so maybe we should think about how that would work.

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1 Just one question I would have is, I don't
 2 know how many people are able to find manuscripts
 3 on places like MetaArchive. So how do we let the
 4 broader public, patient stakeholder community know
 5 that a manuscript is available for review on one of
 6 those sites? I would have to be educated about the
 7 answer to that question.
 8 DR. HAROUTOUNIAN: Maybe we can leverage,
 9 really, the infrastructure and people who are in
 10 this meeting, whether it's resources that PCORI may
 11 have, or some of the patient organizations, or
 12 patient advocates may have, or the Maryland group
 13 may have. I think there are probably some
 14 opportunities for outreach to solicit some
 15 response. But again, I do agree with Bob, with the
 16 point of how do we get, actually, to broader
 17 representation since people are not going to log
 18 into MetaArchive and find that IMMPACT manuscript
 19 and voluntarily respond to it?
 20 DR. KERNS: If I may make one additional
 21 comment on that point. I do want to bring up the
 22 issue of the digital divide, in that there are many

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1 disadvantaged -- in fact, I think we're becoming
 2 clearer about social determinants of pain and
 3 chronic pain, and some of the most disadvantaged
 4 people are at the highest risk.
 5 So if we are going to take that kind of
 6 step, I do think we have to think about how do we
 7 reach those people that don't have internet access,
 8 for example. Thank you.
 9 DR. HAROUTOUNIAN: A very good point.
 10 Alright. Thanks so much. McKenzie had her
 11 hand up.
 12 DR. FERGUSON: I was just going to put a
 13 comment in the chat, and I think Chris has spoken
 14 to this earlier, about the value in clarifying the
 15 roles of the patient partners across the whole pain
 16 research continuum. Maybe by doing that, we can
 17 really show the researchers that it can be a
 18 scalable approach. I think it seems a little
 19 overwhelming to think about all the roles that PPIs
 20 can have, so maybe by delineating that at each
 21 point in the process, it can be somewhat manageable
 22 for researchers.

1 Also within that, I really like the idea of
 2 then going back to patients and saying what would
 3 be the priority within these roles that you think
 4 you can add in terms of where we should be focusing
 5 our efforts if we can't take on the whole approach.
 6 DR. HAROUTOUNIAN: If anyone has particular
 7 feedback or thoughts on McKenzie's point?
 8 (No response.)
 9 DR. HAROUTOUNIAN: I was wondering how we
 10 can address that in a manuscript, in a sense that
 11 would it be a part of, for example, a table? If
 12 we're talking about the life cycle of translational
 13 research, then maybe the same way, we would have
 14 some sort of a figure with increasing roles or an
 15 increasing patient engagement component, I guess,
 16 based on availability, or training, or resources,
 17 and investigators could potentially implement.
 18 I guess a little patient engagement is
 19 better than no patient engagement, and strong and
 20 meaningful engagement is better than a little. How
 21 can we potentially frame it?
 22 DR. FERGUSON: I guess I'm a figurative

1 supplemental table because it could be very long.
 2 But I don't worry about people feeling overwhelmed
 3 by that. I think the point is that they would,
 4 hopefully, read down it and decide what they need
 5 and what they don't need.
 6 The point I wanted to make just before your
 7 comment is, as somebody who teaches about how to do
 8 clinical trials, a huge component of that, the
 9 biggest deficit to all clinical trials, is
 10 recruitment and enrollment. And it's very clear,
 11 in the studies I've been involved in with active
 12 patient partners, that they have a tremendous role
 13 in helping us understand how to approach the
 14 patient population we're interested in and getting
 15 them excited about participating and being involved
 16 in what we do.
 17 So as a thought that I haven't really had
 18 from this particular conference, I'm teaching a
 19 course next semester in clinical trials, and one of
 20 the things I would very much like to have is a
 21 table to show the students and say, "Here's where
 22 your biostatistician works. Here's where your

1 person, so I envision a figure where you kind of
 2 have pre-trial main stage and post-trial rules of
 3 engagement; then within that, very actionable items
 4 where the patient partners can play a role on the
 5 team. Then just by visually laying that out, the
 6 researchers then can say, "Well, I can afford to do
 7 this, and strategically this is where I'm at in the
 8 continuum with my project now; or in future design,
 9 maybe I need to back up and consider pretrial
 10 because I wasn't able to do that now."
 11 DR. FARRAR: Simon, this is John Farrar. I
 12 had my hand up, and it ties right into what
 13 McKenzie is saying; so if you're looking for
 14 additional comment.
 15 DR. HAROUTOUNIAN: Yes.
 16 DR. FARRAR: What I had in my mind's eye was
 17 more or less a table, McKenzie, which would say
 18 here are the things that you need to do in any
 19 clinical trial and here are the contributions that
 20 can be made by getting a patient partner or
 21 stakeholder involvement. In talking about how it
 22 gets published, that might end up being a

1 epidemiologist works. Here's where the geneticist
 2 works, and this is what your patient partners can
 3 contribute. And they can contribute, probably, to
 4 all or many of the different components, providing
 5 a different perspective."
 6 So that's just from the perspective of the
 7 design of the clinical trial, the early part, and
 8 then obviously it carries through to during the
 9 conduct of the trial. I've never been on a trial
 10 that didn't run into real problems as it was
 11 starting, and the patient partners can contribute,
 12 and have contributed, very substantially to that.
 13 Then thinking about how the paper gets
 14 written and what the important features of the
 15 outcomes we get that they need to be part of.
 16 Then, as we've talked about here, disseminating
 17 that information and getting it out there so that
 18 it gets applied. It seems to me that if we talk
 19 about it from the same perspective as the other
 20 important members of the team, it makes it much
 21 more real and much more direct.
 22 Simon, what I'm encouraging is that we make

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1 the point that -- I'm old enough. I remember when
 2 statisticians were not considered an important part
 3 of the randomized-controlled trial, and now you
 4 can't write one without a statistician. I think
 5 that applies to our patients.
 6 DR. HAROUTOUNIAN: Right. I agree. And
 7 it's both ends. It's both the training initially,
 8 but also I think Mark and Frank highlighted in
 9 terms of journals, if you have a mandatory or
 10 recommended component that's describing the
 11 patient-partner involvement, it sort of sets the
 12 stage that this is something that is expected to
 13 do, or this is the practice.
 14 Christine I think mentioned yesterday that a
 15 part of this component, the training in the North
 16 American Pain School, it has become almost an
 17 integral part of teaching about clinical studies
 18 and clinical trials, and I think in most training
 19 programs, this is not a thing. You think about
 20 outcomes development, primary outcome measure, and
 21 randomization blinding, but patient engagement as
 22 partners, it's not something that is taught. I

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1 think as we're aiming for an impact for this
 2 manuscript, I think this is definitely a component
 3 that is worth discussing and bringing some examples
 4 on how this can be done.
 5 I know that Mark Jensen's hand was up, so
 6 maybe, Mark, you can address it from a general
 7 perspective as well, but also hit other comments.
 8 DR. JENSEN: I'm going back to the table
 9 because I'm really resonating with this idea that
 10 Jan raised, that the amount of involvement might
 11 increase as we go from early basic to phase 1,
 12 phase 2, and phase 3. And these papers, these
 13 IMMPACT papers, are very impactful, and in my view
 14 are impactful to the extent that they make strong
 15 recommendations that say, "You know what? Do
 16 this."
 17 So if we can get to a point where we can
 18 say, "You know, you really need to do this," I'm
 19 envisioning a paper where it goes from basic
 20 science, through different phases, and then a
 21 column that says, "You know, we think that for each
 22 of these phases, you really have to do this. This

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1 is just critical for us moving forward," and just
 2 drawing a line in the sand. Then maybe a third
 3 column says, "You know, this would be a good idea,"
 4 and we think it'd be good.
 5 But I think that could give the reader real
 6 clear guidance, and that would also help us editors
 7 go, "You know what? If there's a consensus that
 8 this column is real critical at this phase, then we
 9 could say to our authors, 'If you're submitting a
 10 paper at that phase, you ought to do this.'" So
 11 rather than a blanket checkbox of why didn't you do
 12 this, kind of what Bob was talking about before,
 13 making it more nuanced and specific to the type of
 14 study that's being considered.
 15 DR. HAROUTOUNIAN: Yes. Wonderful. This is
 16 very helpful.
 17 I have Isabel Jordan next, and then Bob
 18 Dworkin.
 19 MS. JORDAN: Hi. I just wanted to go back
 20 to -- I can't remember who it was; it was a little
 21 while ago -- talking about that we all kind of said
 22 the people that are here are already quite

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1 privileged in that we all have bank accounts. This
 2 system is set up for us, and there are barriers for
 3 patients to participate in any kind of research
 4 endeavor as a patient partner.
 5 A lot of us look at engaging with patient
 6 partners as, well, of course, we can send them a
 7 check, or electronic funds transfer, or we can send
 8 them an email. This is true from working with a
 9 research team, to working at an institute, or
 10 communicating with a journal.
 11 I think it's really important to think about
 12 who's making these decisions about how these
 13 systems work and who we're leaving out of these
 14 decisions about how this works, and how we can
 15 overcome this. I think it's really important to
 16 think about, even with journals and doing reviews,
 17 are we engaging with patient partners to inform our
 18 actual engagement work? So not just a patient
 19 partner with lived experience on a project, but are
 20 there patient partners, people with lived
 21 experience, that are actively working with us on
 22 how to engage, looking at the process of engagement

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1 so that we're not leaving people out just by the
 2 systems that we have.
 3 I think it's a huge barrier that leaves
 4 people out throughout the entire process, without
 5 many of us even noticing that we're doing that. I
 6 think it's monumental. And it doesn't matter
 7 whether it's in pain and clinical trials, in this
 8 case, engagement is engagement, and it's a barrier
 9 everywhere.
 10 I think it'd be really important to talk
 11 about this in the how tos because it's the
 12 responsibility of the researcher when you're
 13 engaging with folks to understand what those
 14 barriers are, and sometimes the only way you can do
 15 that is if you've already talked to somebody who
 16 has some understanding of that.
 17 DR. HAROUTOUNIAN: That's a very important
 18 point, Isabel, and also thinking not only about
 19 global resource, for example settings, but also
 20 geographically across the globe, I think some of
 21 those recommendations that we make, we need to be
 22 very thoughtful that they are applicable not just

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1 in Europe, United States, and Canada, but rather
 2 high-quality research conducted elsewhere. And we
 3 need to be thinking about those things that are
 4 applicable for a different setting [indiscernible].
 5 Thank you.
 6 Bob Dworkin?
 7 DR. DWORKIN: I think I'm about to disagree
 8 with a bunch of people. When we first started
 9 thinking about this meeting, probably a year ago,
 10 the focus was going to be on patient engagement in
 11 clinical trials. And then at some point, I think
 12 about three or four months, maybe five months ago,
 13 it was extended to clinical pain research.
 14 We've done no preparation whatsoever about
 15 patient engagement in basic science. Allan Basbaum
 16 has been in this meeting, partly. Jim Eisenach has
 17 been in the meeting for the last few days, but we
 18 haven't asked them what they think about patient
 19 engagement and basic research. We haven't had a
 20 systematic review. We haven't invited any basic
 21 scientists. Jim and Allan are here because they
 22 are members of ACTION's steering committee.

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1 So there's been zero preparation to,
 2 actually in any meaningful thoughtful way, consider
 3 the role of patients in basic science research.
 4 And I would make the same argument about phase 1.
 5 Phase 1 studies are a whole different animal. So
 6 personally, I have zero expertise in phase 1
 7 studies with pharmacokinetics and, obviously, know
 8 nothing about it. I don't even get to say anything
 9 about it as far as I'm concerned.
 10 So, I actually would suggest that to make
 11 Simon's life easier, because he has a life outside
 12 of preparing this draft manuscript, that we keep
 13 the focus on patient engagement in clinical pain
 14 research and try not to tackle things that we are
 15 not prepared to tackle, because we haven't invited
 16 the right people to the meeting.
 17 So that's my two-cents worth. I know Simon
 18 has a family and a career, and if we broaden this
 19 manuscript to a monograph or a book, he's not going
 20 to see his wife and kids for the next year and a
 21 half.
 22 DR. HAROUTOUNIAN: I appreciate the

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1 sentiment, Bob, but I think we should probably keep
 2 the focus on what's going to be a high-impact
 3 output from this meeting. But you have a perfectly
 4 valid point in terms of just our preparation for
 5 the meeting, because this is a topic that can be
 6 done -- if this component of the manuscript is
 7 going to be done outside this meeting, going back
 8 to the literature and identifying things, this can
 9 be prepared as maybe a separate project where
 10 people would volunteer.
 11 I see that there are some comments in the
 12 chatbox about limiting the scope.
 13 Lynn?
 14 MS. LAIDLAW: Sorry. I missed a lot
 15 [inaudible – audio gap]. My WiFi was terrible. As
 16 I'm thinking about a publication and whatever, I
 17 always come back to what really matters. I think
 18 what we heard over the past couple of days is that
 19 it was values that mattered. I would hate to see
 20 that we are putting forward patient engagement or
 21 patient public involvement as an asset when it's
 22 not, when it's driven by values, and you can work

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1 out how to do it. But the most important thing is
 2 coming at it with the right values, and then you
 3 maybe don't do the harm that Isabel talks about and
 4 that I have experienced as well. There's a saying
 5 in co-production that co-production is a state of
 6 being, not a state of doing. So you've got to be
 7 in the right state of being first, and then you do.
 8 I just wanted to say a bit about evaluation,
 9 and just the essential tension and these productive
 10 tensions between something that I think is based on
 11 rights -- well, came out of rights -- that has
 12 been recertified. I don't know any patient
 13 partners that get involved to be evaluated. And
 14 what are you evaluating? Are you evaluating the
 15 difference you let me make or the difference I
 16 could have made if I had some power over my
 17 involvement?
 18 I'm doing a bit of research at the moment as
 19 a patient researcher, as a patient partner. How do
 20 I evaluate the impact that has had on me as a
 21 person, which has been absolutely profound? How do
 22 you evaluate that? How do you evaluate the impact

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1 that patient public involvement can have on people?
 2 It's all bound up in it. So I understand
 3 why you want to evaluate, but maybe we just need to
 4 keep in mind that, actually, you can't always
 5 measure what's really important. And the patient
 6 partner, it's maybe not like other things in
 7 research, and maybe we just have to accept that we
 8 can't evaluate all of it. And sometimes we need to
 9 stop to say, "You know what? This is good, and we
 10 think it's good, and we don't have to justify
 11 that."
 12 DR. HAROUTOUNIAN: Thank you, Lynn, for this
 13 comment. I think it's an interesting and
 14 intriguing point. I think some of us may be sort
 15 of Lord Kelvin followers in the sense that one of
 16 his favorite quotes is, "If you cannot measure
 17 something, you cannot improve it." And I wonder
 18 how do we -- as you said, can we agree that this is
 19 good and not necessarily go into the particular
 20 details? How do we agree that this is good? We
 21 might be a very biased group. I think it's really
 22 interesting to think about how do we assess and

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1 convince others that this is the right thing to do.
 2 I was really interested in your point about
 3 how do we assess what happened to the patient
 4 partners who were involved in their own
 5 perspective. How did that affect? But I think
 6 it's almost a separate question from what we have
 7 for this meeting in a sense that it's thinking
 8 about how we improve the clinical trials. I don't
 9 know if other things, like whether the effect of
 10 participants' engagement on the patient partners
 11 need to be measured as a part of this particular
 12 endeavor. I think it's, separately, a really
 13 interesting and intriguing question.
 14 MS. LAIDLAW: I'm not going to take up any
 15 more time, but there's a couple of really
 16 interesting papers that I'll put in the chat about
 17 the impact of patient and public involvement or the
 18 engagement on the researchers, which then has an
 19 effect on the research.
 20 DR. HAROUTOUNIAN: Which is another question
 21 that is probably outside of the scope.
 22 MS. LAIDLAW: And why isn't that as valid as

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1 some other metrics that we might -- I just really
 2 want to push back against this a bit.
 3 MS. VEASLEY: I think that can be one really
 4 important recommendation. Maybe you missed a
 5 little bit of the discussion earlier. It was to
 6 identify the goals and what each of the
 7 stakeholders in the research group would consider
 8 success, and to measure all of that.
 9 This meeting also hasn't talked about the
 10 need for multistakeholder groups. Sometimes you
 11 need primary care providers, or clinicians, payers,
 12 and all types of other stakeholders to be part of
 13 the research group. We all come to it with a
 14 different background and different perspective, and
 15 we all have different definitions of what success
 16 means.
 17 But I agree with you that we can't measure
 18 everything. I think we need to state that. Not
 19 everything can be measured, but here are the types
 20 of things that we feel could be measured and would
 21 be impactful to measure; not just what is the
 22 impact of patient engagement on the science or

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1 research, but vice versa. Like you said, what's
 2 the impact of our engagement or other stakeholder
 3 engagement on the research team or other
 4 stakeholders? So I think that could be a really
 5 important recommendation.
 6 DR. HAROUTOUNIAN: Thanks, Chris, for
 7 pointing this out. I think in terms of what
 8 success looks like, for the same team of
 9 investigators, for example, with patient partners
 10 and everyone -- for example, for the PI, publishing
 11 the paper in JAMA may be the point that is
 12 considered a success. If it's an industry trial,
 13 maybe getting a drug approved would be a success.
 14 From the patient partner perspective, getting
 15 something that can help the condition with less
 16 side effects, that is a success. And this will
 17 look completely different in how we prioritize
 18 which are more important to measure as a success of
 19 the program.
 20 I think there's really a point about there
 21 are several things to measure. There are probably
 22 different ways to approach them. And we also need

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1 to realize that we may be unable to measure all of
 2 those things in any meaningful way. So I think
 3 it's probably lending to a nice paragraph that is
 4 addressing some of those points.
 5 I think Jen has her hand up, and then Ian.
 6 DR. GEWANDTER: Hi. Thanks. I guess I'm
 7 coming to this probably as one of the more naive
 8 people in the room because most of my patient
 9 engagement has been more on the qualitative
 10 interview, so more of the research way than in a
 11 partnering way. So I feel like I've learned a ton
 12 today, so thanks everybody for all of your
 13 thoughts.
 14 So I guess as someone who would probably be
 15 a consumer of this manuscript, maybe more than an
 16 author, I think, for me, what would be really
 17 important -- because, to me, it's a lot less
 18 overwhelming, the idea of getting patients' input
 19 or people with lived experience input on a
 20 particular specific study idea I have. And what's
 21 more overwhelming and scary to me, kind of as
 22 Isabel pointed out, is this concept of trying to

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1 establish these long-lasting relationships, and how
 2 to do that, and what do I bring to the communities
 3 to make them want to engage with me, especially
 4 underserved communities as like a middle-aged,
 5 white lady.
 6 I think maybe not like a detailed how to,
 7 but at least some references, two examples, of how
 8 that's been done well like -- sorry, I forgot her
 9 name -- the person who talks about their work in
 10 Maryland. Those kinds of things I think would be
 11 really helpful for me as someone who is reading
 12 this manuscript.
 13 DR. HAROUTOUNIAN: No. Thanks so much.
 14 Maybe I can share the slides for a second.
 15 Some of the things that we heard -- and I think in
 16 the manuscript we should be addressing them maybe
 17 in an order -- is thinking about the process. Once
 18 we determined that it's important to engage
 19 patients and partners, I think we had a lot of
 20 material presented on thinking about how to
 21 identify, locate, and incorporate patients in the
 22 planning. We had quite a quite a bit of

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1 information there.
 2 I think John's suggestions in the
 3 presentation on how to think about including
 4 diverse and hard-to-reach population partners in
 5 that group, that probably, I think, needs another
 6 component; incorporating patients in the conduct of
 7 the clinical study, as well as, eventually,
 8 dissemination and implementation.
 9 I think maybe another point, really, Jen,
 10 that we could think about is how to maintain those
 11 partners and what might be the strategies to
 12 actually building the trust component. I think one
 13 thing that maybe we barely touched it because it
 14 wasn't presented formally, but maybe a little as a
 15 chat conversation, was involvement in the data
 16 analysis and interpretation component.
 17 I think there were some views that maybe
 18 patients may not have as much to say, but I think
 19 actually that's going to the question of who
 20 decides where patients voices are important or not.
 21 I think there was actually quite a bit of input
 22 that patients should be involved in thinking at

1 least about data analysis. Maybe they will not be
2 running your regression in R, but in terms of
3 providing valuable input on the metrics and how we
4 interpret the data, it's also probably worth
5 addressing along those specific recommendations.

6 I think we did discuss how to measure
7 success, and Dr. Forsythe really brought this
8 plethora of information, and then mentioned 35 to
9 40 different tools that may be existing out there
10 for measuring at least some of the components. I
11 guess the question is we don't envision -- or I'm
12 not sure we can hope to come up with a specific
13 tool for assessing success in specific domains, but
14 at least providing some recommendations of what
15 researchers may think about using and potentially
16 implementing in particular settings. So thanks,
17 Jen, for that point.

18 Back to Ian.

19 DR. GILRON: Yes. Thank you. My comment
20 also has to do with measurement and also the fact
21 that we're early on in this. I felt more urgency
22 to make the comment when I heard Mark Jensen saying

1 patient partners.

2 Another example is, does a patient have to
3 be blinded to their treatment allocation until the
4 entire database is locked for a clinical trial? It
5 would seem nice for them to know as soon as
6 possible, but if they continue to be in touch with
7 research personnel, there's potential for
8 unblinding.

9 I just have some examples of potential
10 threats, where patient partnership could
11 potentially have an impact on scientific quality,
12 and that's just something that we need to be aware
13 of and to negotiate. But just put that as a
14 placeholder in the manuscript, that we're going to
15 follow this process as we go, and we may have to
16 make some course correction along the way.

17 DR. HAROUTOUNIAN: A really good point. I
18 think it does come back to the point that Sean
19 Mackey brought about those potential conflicts and
20 how to resolve them. I think some of the
21 suggestions of being transparent up front and
22 defining roles, the way that each partner has an

1 that this needs to be mandated now in articles, and
2 people need to show that they've involved patient
3 engagement.

4 I like that you have how to measure success.
5 I wonder if we should change it to how to measure
6 impact. And in particular, there are certain
7 aspects that we don't need to measure that we know
8 we appreciate inherently that this is an important
9 thing to do and that we should be doing this, but
10 we should be mindful of potential threats. I'll
11 just give some simplistic examples, and they're not
12 necessarily a concrete example, but they're just a
13 way of illustrating some things.

14 For example, in a study where you want to do
15 pharmacokinetics, and if you ask a patient partner,
16 they say, "Do you really have to stick me for
17 phlebotomy to do this test?" We just want to make
18 sure that the science of what we're doing is not
19 necessarily compromised, and there may be some
20 challenging conversations with patient partners to
21 sort of explain or defend certain things that are
22 critical for science that may not be popular to

1 [indiscernible]. And John Farrar mentioned that if
2 you're a statistician, you have a particular role,
3 and being transparent and clear in communication up
4 front so that expectations are set about the
5 decision-making processes. But also what Simon
6 mentioned, considering that everyone is equal
7 around the table in terms of how we think about out
8 people's input, even though not everyone can have
9 cake every day.

10 I think it's a really important point, and I
11 think we'll have to address that in the manuscript
12 in some way that these are potential roadblocks or
13 costs, and here are some suggestions, based on the
14 presentations that we heard, that researchers can
15 think about in terms of overcoming them.

16 Ewan had his hand up.

17 DR. McNICOL: It's Ewan. I just had a
18 couple of quick thoughts on the manuscript.
19 Usually when we do this -- I think we're all kind
20 of familiar, or most of us are familiar, with what
21 the IMMPACT manuscripts look like after these
22 meetings -- typically the way they finish up is

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1 that we have these universal recommendations for
 2 how we'd like to see things changed.
 3 I think in this instance, the
 4 recommendations need to be based on the individual
 5 stakeholders, from a patient perspective, from a
 6 researcher perspective, from an industry
 7 perspective, et cetera, and the recommendations
 8 will vary based on who those stakeholders are.
 9 Further to that, Jennifer mentioned that she
 10 was kind of new to this whole thing, and this
 11 broadly is in its infancy. I wonder if in our
 12 recommendations we can make short-term
 13 recommendations, or recommendations based on -- if
 14 you'll just start with what's the small thing I can
 15 do right now versus these loftier or long-term
 16 goals that we may factor into it.
 17 So maybe we can divide it into either a
 18 continuum or short versus long-term, small versus
 19 big, because I think some investigators are just
 20 feeling a little bit overwhelmed engaging patients
 21 and where do we even start with this. It's easy
 22 enough to reach out to an organization, but it's

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1 much more challenging to reach out to an
 2 underserved population, for example, and where do
 3 you get the time, and the money, and the resources
 4 to help with that?
 5 That was it. I was just piggybacking on to
 6 what Jennifer had mentioned earlier.
 7 DR. HAROUTOUNIAN: Thanks, Ewan. I'd be
 8 really happy to hear what people's thoughts are on
 9 dividing the recommendations based on different
 10 stakeholders, whether it's regulators, funders,
 11 partners, and investigators.
 12 Karen, I see your hand up.
 13 MS. MORALES: Yes. I just wanted to reflect
 14 back on this concept of how do you bring
 15 participants into the process at the very beginning
 16 when you're planning. One of the things the
 17 PATIENTS program successfully was able to do was to
 18 partner from the program level as opposed to
 19 thinking about it from the specific project level.
 20 We brought participants in on our budget line at,
 21 literally, the PATIENTS Program budget. We
 22 actually utilized some of our unrestricted funds to

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1 be able to incorporate patients and community
 2 participation at the very top level. That was
 3 suggesting that we really appreciated and valued
 4 their input as to the direction in which our
 5 program was going; as to the types of projects that
 6 we would bring into our program and what we would
 7 go after and the type of funding we would go after.
 8 They actually were part of designing how we
 9 would move forward, and our patient representation,
 10 our other community partners, and our other
 11 organizational partners have a voting. Their
 12 voting rights were greater than ours as an
 13 organization. So if the patient group or our
 14 community partners voted 7 to our 5 or our 6, then
 15 we went with whatever they suggested and
 16 recommended.
 17 So that's how we move forward with being
 18 able to incorporate them at the very planning level
 19 because it's not just about planning the projects;
 20 it's about planning your strategy as well and how
 21 you're going to move forward as an organization.
 22 DR. HAROUTOUNIAN: Yes. This is a really

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1 great point, Karen. Thanks for bringing it.
 2 I'm wondering, as a part of our
 3 recommendations maybe to funders as
 4 stakeholders -- as you said, the University of
 5 Maryland may have been fortunate in the sense that
 6 you may have some unrestricted funds to start the
 7 conversation or initiate some outreach, but most
 8 funding programs don't have that piece of money,
 9 where it's take this money and spend two years of
 10 building those community partnerships.
 11 Are there certain recommendations that we
 12 can make to maybe make new opportunities for
 13 funding, or new announcements that would be
 14 targeted specifically in the training component,
 15 but also building those partnerships and initiating
 16 programs? And again, I might not be aware that
 17 there might be several funding mechanisms for that
 18 already, but that's definitely not the commonplace,
 19 and I would assume most institutions don't have
 20 something in place already for researchers to tap
 21 in.
 22 MS. VEASLEY: Simon, if you're asking --

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1 DR. HAROUTOUNIAN: Yes, I am.
 2 MS. VEASLEY: -- I was just going to say one
 3 recommendation for funders is something the HEAL
 4 Initiative has done, and Rebecca talked about it
 5 before, is they've put out supplemental FOAs for
 6 engagement specifically. It was kind of an
 7 afterthought because it wasn't included in the
 8 first initial round of funding, but that's one
 9 potential recommendation.
 10 There could be specific awards that go up
 11 from NIH, or funding agencies, to specifically
 12 support pre-engagement efforts. Another thing they
 13 could do is to build into the actual grant a stage
 14 for planning for community engagement and time. So
 15 maybe it adds another 6 months, or 9 months, or
 16 12 months into the grant, but that could be one
 17 pre-planning phase before they launch into the
 18 study. I don't know what others think about that.
 19 DR. HAROUTOUNIAN: That's a good point, and
 20 I agree. I think the HEAL Initiative, the
 21 additional supplemental FOA is for HEAL
 22 investigators, so people who are already funded by

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1 HEAL if I'm not mistaken. So it is, to some
 2 extent, and afterthought, but still nevertheless
 3 important.
 4 DR. DWORKIN: HEAL, PCORI is very
 5 US-centric, and I would be in favor of a
 6 recommendation that was really international, which
 7 is that we would recommend that medical schools
 8 have available the kind of program that we heard
 9 about from Maryland and the kind of program that
 10 Jonathan Jackson has at MGH Harvard. I heard last
 11 night that Vanderbilt has a similar program, and
 12 there are medical schools all over the world.
 13 So I would advocate for being less
 14 US-centric and more international, the
 15 recommendation.
 16 Jen and John Markman, if you'd correct me if
 17 I'm wrong, but I'm pretty sure that we don't have
 18 here in Rochester the kind of programs that Karen's
 19 describing in Baltimore or that Jonathan Jackson
 20 described in Harvard. And I think it would be
 21 great to have something like that at our medical
 22 school, and with every medical school in the world,

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1 and I don't see why we can't have that as a
 2 recommendation.
 3 DR. GEWANDTER: Our CTSI has some stuff, but
 4 I don't think it's as advanced as what Karen was
 5 describing. I think the other thing, a little bit
 6 for me -- we are an EPPIC-Net site, so I've been
 7 thinking a lot about trying to establish this
 8 myself for our pain group.
 9 It's kind of important that we have
 10 relationships for our specific areas, too. For
 11 example, if we had like an interdepartmental pain
 12 research program at the university, if we could
 13 somehow support this effort, because you're not
 14 always engaging the same people as like a whole
 15 medical school.
 16 So I think that's where the challenge is.
 17 Even though the CTSI has these community engagement
 18 studios and stuff like that, and may have some
 19 existing partners, it's not necessarily the right
 20 people for me. So I feel like I have to still
 21 maybe use them as a resource, but would have to
 22 make my own connections and my own relationships

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1 like an investigator. It's kind of how I'm
 2 starting to approach it and feel about it.
 3 DR. DWORKIN: But if we had someone like
 4 Karen or Jonathan Jackson at the medical school,
 5 they would be able to help us do exactly that. I
 6 personally think every medical school should have
 7 Karen or Jonathan on the faculty.
 8 DR. HAROUTOUNIAN: I see Karen wants to
 9 respond to that specifically.
 10 MS. MORALES: Yes. I just wanted to say
 11 that's where your partnerships come in, because we
 12 have partnerships with Morgan and we have
 13 partnerships with Coppin. We have partnerships
 14 with other institutions who were not as versed in
 15 this when we first started it in 2013. So as we
 16 started to grow and we partnered with other
 17 organizations in the Baltimore area, they're coming
 18 on board.
 19 There was a question yesterday that was
 20 asked were there other institutions, as far as
 21 universities, also taking this up as an uptake in
 22 patient engagement. And I did say yes, I do see

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1 that other institutions are now willing to partner
 2 and to utilize this patient engagement concept as a
 3 framework for how they move forward in their own
 4 research, and they're taking it to their students.
 5 The PATIENTS Program is actually currently
 6 developing the PATIENTS Professor Academy, as Gail
 7 mentioned yesterday. We're in the very infancy,
 8 but we're raising funds. We've already had
 9 commitments from three different organizations to
 10 support us at the \$100,000 level each.
 11 So this thing is growing, and I do believe
 12 that if you were looking at your existing partners,
 13 your existing relationships, and bringing them into
 14 this new engagement paradigm, it may take some
 15 time, but, Jennifer, you'll definitely be able to.
 16 If you're partnering with other groups around you,
 17 I think you'll be able to move that needle in being
 18 able to get into the communities.
 19 DR. HAROUTOUNIAN: Thanks so much, Karen.
 20 Isabel?
 21 MS. JORDAN: It's really great comments on
 22 the need for training, specifically for engagement.

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1 It's really important. I think it's also important
 2 to recognize that if people are going to require
 3 patient engagement on projects, that funders
 4 specifically fund that engagement. If done well,
 5 we talk about that risk of trauma, the risk that it
 6 could go wrong, then having people have the
 7 necessary budget, time, and funding for this, and
 8 then somebody actually needs to fund that budget
 9 piece. I think that's a really important
 10 recommendation, and it's beyond the side of desk
 11 operation.
 12 DR. HAROUTOUNIAN: Yes, I agree.
 13 Before we go back to this initial
 14 structure -- and I think the comments were
 15 extremely valuable. I think there's a lot of work
 16 to do, to sift through them and see what's the best
 17 approach to organizing them. I'm not sure where
 18 we're having a consensus on many of those points,
 19 but probably with your input on some of the initial
 20 versions of the manuscript, we might be able to
 21 focus and reach some consensus on some of those key
 22 points.

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1 We have a few minutes left, and I want to
 2 give an opportunity to anyone who hasn't had the
 3 chance to raise any points related to either the
 4 manuscript or comments on the presentations, either
 5 from today or earlier; that we may have a few
 6 minutes to address before wrap up.
 7 Bob Kerns?
 8 DR. KERNS: Yes. Forgive me if this has
 9 already been emphasized and I missed it. I've been
 10 concerned -- and a few of you have heard
 11 this -- about barriers in the context of, for
 12 example, NIH, or particularly NIH program
 13 announcements or RFAs, that are even explicitly
 14 encouraging engagement of patient partners or
 15 people with lived experience.
 16 The timeline between the publication -- even
 17 a notice of intent, let alone the publication of
 18 the RFA or program announcement -- doesn't really
 19 adequately provide a feasible timeline unless
 20 you're embedded in an organization that already has
 21 an active patient engagement group and you can
 22 readily tap into them quickly.

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1 I do think that there's a fundamental
 2 challenge at the very beginning of trying to really
 3 engage people with lived experience, even
 4 identifying key questions, or alone, helping the
 5 design and methods.
 6 My recent experience, by way of example, is
 7 the IMPOWR RFA that explicitly called for
 8 engagement of stakeholders, including people with
 9 lived experience. I think our group at Yale did a
 10 great job. We have a lot of partners. We have
 11 individual conversations and so forth, but the
 12 bottom line was it was the investigators that drove
 13 the train to the finish line and getting the
 14 application in. And now we have an opportunity to
 15 really more fully engage partners in a way that
 16 really wasn't available to us up front.
 17 If that was already emphasized, I do think
 18 that it's a challenge, mostly for -- I mean, it's
 19 really our whole community, but I think it is
 20 sponsored. I see Laura shaking her head in
 21 particular, so maybe it's even true with PCORI.
 22 DR. HAROUTOUNIAN: Yes. It does come back

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1 to Bob Dworkin's point of whether our
2 recommendations can be either institute specific,
3 or country specific, or more global. And I don't
4 know whether UK or Canadian organizations also have
5 these short timelines. It's something that might
6 be worth looking into and maybe providing some sort
7 of comparison.
8 But I think a general recommendation to
9 allow enough time and potentially provide
10 preliminary resources for meaningful engagement of
11 individuals with a lived experience, that's almost
12 an easier recommendation to make. The question is
13 how to formulate it for it to have an impact.
14 DR. KERNS: Really, I think there are
15 multiple issues here. Money and time; none of us
16 want to extend the whole timeline of an idea to
17 implementation, so that's obviously an issue. But
18 I will also add that I think it speaks specifically
19 to emerging areas of interest around special
20 populations, subpopulations of people with pain or
21 pain and comorbidities, like people with chronic
22 pain in opioid-use disorder, for example, where you

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1 aren't likely to have the right mix of people
2 already there when you start to develop here.
3 DR. HAROUTOUNIAN: I agree.
4 It looks like Laura Forsythe may have some
5 comments to that.
6 DR. FORSYTHE: I was just going to say I was
7 nodding, Bob. We hear a lot about that. I think
8 it's a real challenge, and probably offline I'd be
9 happy to talk with you about a couple of the things
10 that PCORI has done to try, in part, to address
11 that, and also invite the opportunity to hear more
12 about what are some other ways to get at that.
13 It's a legitimate challenge, I think, that has a
14 variety of factors that affect timelines for
15 things, too. So I would love to continue that
16 conversation.
17 DR. HAROUTOUNIAN: Thank you.
18 I think one component that we maybe didn't
19 address as thoroughly in those two days -- we
20 talked about patient engagement and planning,
21 conducting research, potentially, and dissemination
22 and endurance [indiscernible], et cetera.

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1 I think the implementation piece was left
2 out a little bit, or to some extent, particularly
3 if there is research with some meaningful results
4 and how do we embed that in the community, and then
5 what's the role of different payers that are
6 involved in that system in terms of how patient
7 partners can help us build some of those bridges
8 and facilitate some of those processes toward
9 actual implementation of research findings in the
10 community?
11 We touched upon that briefly, but if anyone
12 has particular thoughts on either approaches or
13 where we might want to look for a little bit more
14 information on that, I think that could be useful,
15 again, for the manuscript.
16 DR. KERNS: Just one comment from experience
17 is our pain management collaboratory and the
18 advantage of engaging a group of dedicated veterans
19 and service members, who themselves are embedded in
20 communities that are important targets for future
21 advocacy and spreading the word, if not actually
22 supporting implementation.

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1 So I think it may be that there are
2 different -- I don't know how other people think
3 about this; I guess we really haven't talked about
4 it. Is there a need to even think about different
5 groups of patient partners or partners with lived
6 experience across a research life cycle continuum?
7 I think it has been mentioned, but maybe to
8 emphasize that point.
9 DR. HAROUTOUNIAN: And I'm sorry I haven't
10 been able to follow the chat if there were some
11 comments that we didn't address or missed.
12 DR. KERNS: Well, I think the bottom line is
13 I've recommended that we're going to
14 have -- there's a lot of rich information there and
15 a lot of people reflecting on each other's
16 comments. I think that's all great.
17 We have to capture this. I think it was
18 Christine or somebody suggested that we'll -- I
19 know we have the capacity to do that. Valorie
20 yesterday captured the chat and fed it to the core
21 group. So we can do that and potentially not
22 burden people with a long, extensive chat document,

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1 but some collating or something that we can
 2 disseminate to the whole group; a lot of great
 3 resources, so thank you, everybody, for your
 4 contributions.
 5 DR. HAROUTOUNIAN: As Bob Dworkin said,
 6 there's a lot of material to work with. It might
 7 take more than a day or two to try to summarize the
 8 responses and any resources, and come up with some
 9 sort of initial draft to get everyone's input on.
 10 DR. KERNS: Well, we gave you till Monday at
 11 noon.
 12 DR. HAROUTOUNIAN: Yes. I think it was
 13 Tuesday, but something in that range.
 14 So thanks, everyone. I truly appreciate the
 15 input and your willingness and energy to provide
 16 really useful and thoughtful feedback, and I'll
 17 pass it to Bob or Dennis for final remarks.
 18 Adjournment
 19 DR. DWORKIN: Thanks, Simon.
 20 On behalf of Dennis and me, I want to thank
 21 all of you for hanging in till the very end.
 22 Dennis and I always feel that our primary goal is

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1 to make sure these meetings end before happy hour,
 2 Eastern Standard Time, and I think we succeeded
 3 today, so that pleases us greatly.
 4 Of course, we owe an enormous debt of
 5 gratitude to Chris Veasley and Bob Kerns for
 6 putting together an absolutely fantastic IMMPACT
 7 meeting. I think we all look forward to the day
 8 when these meetings will be in person in some hotel
 9 in the Washington DC area, but given that we're not
 10 there yet, this has been a terrific virtual
 11 meeting. And really, I think IMMPACT and ACTION
 12 are going to use it as a touchstone in designing
 13 future meetings.
 14 Of course, we all owe an equally enormous
 15 debt of gratitude to Valorie and Carlos because
 16 this wouldn't have happened without their help,
 17 from A to Z, and all the technical support, and the
 18 kind of stuff that's been going around the edges of
 19 this meeting before, during, and after.
 20 Finally, in terms of thank yous, I want to
 21 thank Simon's wife and children for freeing up the
 22 hours that he is going to be devoting to bring this

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1 manuscript over the publication goal line. So on
 2 behalf of all of us, we will be sending something
 3 to Simon's family to acknowledge our deep gratitude
 4 to them for freeing up his time.
 5 Dennis, have I left anything out? I just
 6 feel enormous gratitude to everybody, and I'm sure
 7 I left something out, Dennis. You're on mute, if
 8 you want to say something.
 9 DR. TURK: You've done a fine job. Thank
 10 you, Bob, for bringing us together toward this end.
 11 The next steps are going to be, as this manuscript
 12 gets drafted up, it will be circulated. Everybody
 13 here who wants to be involved as an author will
 14 have opportunities to have input into that. So
 15 don't think that this is over when this meeting
 16 ends, but rather this is the end of the beginning
 17 of what you're going to be seeing.
 18 We do encourage those of you that do become
 19 involved with commenting on the manuscript to do it
 20 in a timely fashion. Given the number of people
 21 who are potentially authors, it really is important
 22 that if you are interested and want to contribute,

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1 you should do it in a timely fashion. And we will
 2 encourage Simon to give you some kind of time frame
 3 to provide responses because we don't want this to
 4 take three years to be submitted.
 5 So thank you, everyone. We look forward to
 6 your continuing participation. The conversation is
 7 not over, obviously.
 8 DR. DWORKIN: And for those of you who
 9 missed it, Dennis was just referring to the end of
 10 the movie Casablanca, that this is the beginning of
 11 a long, beautiful friendship, not the end of an
 12 IMMPACT meeting. Thank you all very much, and have
 13 a great weekend.
 14 MS. VEASLEY: Thank you, everyone.
 15 (Whereupon, at 2:30 p.m., the meeting was
 16 adjourned.)
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