PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

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# AGENDA

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CHAIRMAN NORQUIST: Good morning. I’m Dr. Gray Norquist, Chair of the PCORI Board of Governors. I want to welcome you to today’s Board meeting, which we are holding in Alexandria, Virginia.

Let me extend a special welcome to those joining us today via webinar and teleconference. Instructions for registering to join us online or by phone are available on our website at PCORI.org/events. All materials presented to the Board today will be available during the webinar and after will be posted on our website, PCORI.org.

The webinar is being recorded and the archive will be posted within the next week.

As with all of our in-person Board meetings, there is a public comment period later today from 4:30 p.m. to 5:00 p.m. Eastern daylight time, and we welcome comments from members of the public here with us in the room as well as those
joining us by webinar and teleconference.

Information about how to offer public comment is on our website at PCORI.org/events, and of course we welcome feedback any time by email to info@PCORI.org or through PCORI.org. We’re live-Tweeting today’s activities on Twitter. Join the conversation at #PCORI.

I did realize I said teleconference, but we’re not teleconferencing today. This is a change for us. We’re only doing audio webinar, so you will not be able to see us, but if you want to see our pictures you can always go to our website and see who we are. That means -- yeah, and you can get rid of the makeup people. That’s a joke. We don’t actually hire makeup people, just don’t want anyone to get that impression.

But that makes it even more important that when you talk, please say who you are so people will know who’s talking.

So, I’m going to introduce now Joe Selby. Oh, I’m sorry. Joe reminded me -- since you can’t
see, three of our Board members will not be with us today, Arnie Epstein, Leah Hole-Marshall and Steve Lipstein, and Rick Kuntz is at a meeting. He had to leave and will be back at some point. There may be — I think, Harlan, are you going off for a little while? Yeah, later, so we may have a few dropping in and out also. Thanks.

Joe Selby.

DR. SELBY: Thanks, Gray, and good morning, everyone. Let’s see if I can advance the slides.

Okay, so good morning and welcome to Alexandria. I’m going to speak briefly on several big items that won’t get discussed much otherwise in the day and those include a brief update on PCORNet, a brief update on our Pragmatic Clinical Studies Initiative, reports back from two advisory panels, the Clinical Trials Advisory Panel and the Rare Diseases Advisory Panel, which just met last week for the first time. We have a welcome of a new executive team member, Jean Slutsky, and then a
brief review of today’s agenda.

So, PCORNet is undoubtedly PCORI’s largest investment to date and it is a genuinely exciting opportunity to transform the way that research gets done in this country, to make it more patient-centered, to make it more involving of all the end users of research, not only patients, but the clinicians who care for them and the healthcare systems where they get their care. It brings together 11 clinical data research networks of a million persons a piece or more, and 18 patient powered networks, which are activated patient groups who are dedicated to participating in research and who will grow and cooperate with the CDRN, the Clinical Data Research Networks, over time.

We’re in an 18-month startup phase right now. I want to point out that we have a steering committee that has a number of potential future funders of PCORNet research including the NIH, the FDA, AHRQ, the CDC. We also have CMS, the Office
of the National Coordinator, ONC, and the Assistant Secretary for Planning and Evaluation, ASPE, because these three represent federal entities that can support PCORNet, and particularly can help us access data that is needed to complete the cohorts that have been built and identify the outcomes that matter to patients and to us.

On the steering committee also are representatives of the medical product, that is pharmaceutical and device industries, because we want to build a network that will support research that’s of interest to them as well as to the federal funders of research.

That’s the steering committee and it also includes PIs from every one of the 29 networks, held together by a coordinating center housed at Harvard, Pilgrim, and Duke, that is very experienced at building and supporting these kinds of networks and charged with 11 major tasks. This is a transformative effort, it’s also a daunting effort, and I will just mention briefly three areas
that we’ve been working on particularly in the early going.

The first is the -- and I noticed that now this is working, good -- the first is data standards and security. To build a network, we don’t transfer data between sites in the network, but we do have to arrange the data within each one of the participating networks in the same standard way, so that we can write programs and codes to do queries and to do analyses. We then pool the analyses. So, this protects data security and patient privacy.

But it’s a lot of work and we have been working hard with our 29 participating networks to agree on early, pretty simple data standards so that we can begin looking at data across these networks without transferring any data.

I want to say too that it’s pretty inspiring, the passion and the commitment that these 29 networks bring. To a network, they appreciate the transformative nature of what we’re
trying to do and they’re tolerant of us in the complexities that we’re running into jointly.

One critical area that we’ve addressed in the last couple weeks with a very successful meeting at the IOM is the notion of how health systems get involved. I mean, we asked them to grant permission for research to be done within their systems, we ask them to eliminate barriers to accessing data, and we will be asking in phase two for their support, their -- hopefully for some financial support for the network to continue.

We held a meeting at the IOM where we heard from -- in discussing many of these issues, and I think it’s fair to say that there was a lot of enthusiasm from the CMOs, the CQOs, and other high level executives within a number of organizations inside and outside of PCORNNet, but the message was also clear, that this research needs -- for them to be genuinely interested, this research needs to be rapid and it needs to be research that serves the interests of health
systems struggling to survive, so it really proves the point that if you want support, you’ve got to be meeting the needs of those who would support it, the end users.

So, very hearty meeting and we will follow it up with a meeting with CEOs at the IOM in June.

The third area, which has received some attention in the last couple weeks, is the critical area of data privacy, and I will say that PCORNet has a number of aspects of it that are already designed to provide additional protections toward securing data privacy, but I think there’s a dialogue to be held with patients, with patients in our Patient Powered Networks, patients in our CDRNs, with the health systems that are participating, and with the community, about what data privacy means and how we optimally balance the great opportunities of these data with the real risks to patient data privacy, how we include patients in the decision making about policies, and also about the particular projects that we’ll
undertake together and in the decisions about when informed consent -- when individual informed consent is needed and when other forms of communication between health systems and the patients are needed.

So, these are three huge areas, not to say that all of these other areas on the right aren’t also going to be big areas to work on during these 18 months.

This is the timeline, and I mainly want to show that we expect to have the first query from the Common Data Model, the Standardized Data Model, September of this year followed by governance policies, but a really big issue is in December of this year we will release an announcement for phase two.

Phase one is only 18 months long. Some sense of continuity is needed by the investigators, by the networks, and by the healthcare systems that host them, and that announcement will come out in phase two. It will be competitive. It will be
awarded at the end of phase one, at the end of September 2015, and it will be open -- our view at this point is that it will be open to additional competitors as well, so others who want to join PCORNet will be able to compete at this time and there will be continued infrastructure funding, but we hope that phase two also is advanced by funding for real research as well as continued building of infrastructure. We expect that.

Okay, that’s all I’m going to say on PCORNet. I want to say a few words now about the pragmatic clinical studies and stop for a minute for --

CHAIRMAN NORQUIST: Hang on, Sharon has a question.

DR. LEVINE: You’ve got a very large steering committee, just looking at that, so I assume that it’s in the -- you know, more than 20 people and I’m just wondering how the work of the steering committee and the executive committee, how that’s divided up.
DR. SELBY: Well, it’s a good question and the executive committee clearly does a lot of the initial thinking, the agenda setting, for example, and then a lot of the work is actually done in the taskforces.

The model is that the taskforces do the work; they generate draft policy. Most of these taskforces have representation from just about all the networks, so that’s how much work is going on, and the policies come up through the taskforces to the steering committee for consideration, modification, and votes.

So, now I’m moving on to a second topic, the pragmatic clinical studies. As you know, we issued our first pragmatic studies announcement in February of this year and received around 270 applications. A number now have been reviewed and invited to submit full applications, which will be reviewed in November, and the first six to nine pragmatic clinical studies, I will tell you that it looks like most of them will be clinical trials,
will be funded in January -- awarded in January of 2015.

But I just put up here, and I’m not going to read through them, but there’s two slides that anyone listening online can -- will be able to see posted on the PCORI website later today, of the topics just to give you a sense of the yield from this announcement. We were very excited by the letters of intent that came in, really looking forward to the reviews and to identifying the projects going forward.

Again, here is the second set. Another announcement for the next round of pragmatic clinical studies goes out later in May, and so those listening should be on the lookout for that if there’s interest.

We’ve really emphasized in these not only that it must be a high priority topic, but also that the applicants must bring along organizations that represent the patients and the clinicians, maybe the policy makers or payers, who would
implement the financials. So, this is really engagement at a very high level and consequently the funding award is large, and so these, I think, will be among the studies that we point to within a year as being emblematic of the way that we do research and the ways that we do it differently.

I’ve already gone through this. The awards will be announced in January and probably the earliest start date would be April of 2015.

So, as I said, the advisory panel on rare diseases met for the first time -- we had actually two remarkable meetings this week, probably more than two last week, but two of them that I attended were the rare diseases and the clinical trials panels.

So, this multi-stakeholder panel with a lot of expertise from various sectors of the rare disease community from federal funders, NIH, to patient organizations, the National Organization of Rare Diseases, industry was well represented, and patients -- there’s a tie to PCORNet and PPRNs on
this panel, but the initial focus was very clearly
that they wished to help us on foundational issues
like issues related to the data standards for rare
disease registries, for issues -- really serious
issues that you talk to the owners of these
registries about early on about policy questions o
who owns the data. What happens to the data if the
funding should run out? How do you sustain a
registry such as this? Policies about access to
the data and issues related to institutional review
boards.

So, there’s expertise on this panel that
will help us both -- with all of those questions.
They want to commission a landscape review on the
set of issues that are uniquely related to rare
diseases. They’re particularly interested in
addressing IRB issues, interestingly as is PCORNet
and their interest is particularly related to rare
disease research, and they want to advise on how we
take the CER framework and use it in rare disease
research.
They will coordinate closely with our advisory panels. This panel does not make decisions about topics to research, but they will interact with our advisory panels to give them the perspective of the rare disease community and they will certainly coordinate with PCORNet’s taskforce on rare diseases. Very successful launch of this committee, very dedicated people on it.

And the very next day we held our first meeting at a clinical trials advisory panel and I think we found also there just a very well suited group of people, a complementary group, a lot of expertise across the range of issues, and they set out -- their mission will be to keep -- remember that the Methodology Committee is closely linked with this committee because they both have a lot of methodological interests and responsibilities.

So, one of their first tasks will be to work with the Methodology Committee to review the standards that are related to clinical trials and keep an eye out for either the need for updates or
for additional standards.

So, I suspect that recommendations for
some new standards will come out of this panel.
They want to provide guidance for applicants on
some of the innovative methods around comparative
effectiveness and pragmatic trials, particularly
adaptive trials using Bayesian methods.

Also in collaboration with the Methodology
Committee, they will work to give PCORI
methodologic consultation at the point where
letters of intent are being considered, at the
point where we actually solicit targeted funding
announcements and pragmatic clinical studies.

So, they will work with us on refining the
solicitations and the letter of intent review, the
process of that, to make it fit better with optimal
clinical trials methods when research is funded.

They will also provide methodologic
consultation along with the Methodology Committee
to reviewing applications, to reviewing the details
of methodologic issues in applications to enhance
the rigor and the pragmatic utility of proposed studies.

They will advise PCORI on developing policies for DSMBs, Data Safety Monitoring Boards, that’s a critical issue that we face particularly as the pragmatic clinical studies come online. And they will work with us on the ethical assessment of low-risk pragmatic trials, particularly issues related to IRB oversight and the need for informed consent.

So, those are the issues that they’re going to help us with and we’re just delighted at the first meeting and very glad to have that assistance.

Okay, now we’re moving into other news. As you know, the legislation called for a five-year review of PCORI by the Government Accountability Office and that process has begun. We received a letter from the GAO in March. He’s identified two primary objectives for the review. The first is, what has PCORI done to establish research
priorities and get research underway, and how does that align with the legislative mandate? So, that was the first broad question they’ll be asking us many details about.

And the second is, to what extent has PCORI established plans and undertaken efforts to evaluate the effectiveness of its work? So, the GAO is very motivated, very oriented towards strategic planning and careful evaluation in light of a strategic plan, and I think we are well served by having our strategic plan in place and by having our PCORI evaluation group in place.

We held our first conference with the team in April and they will be returning for a series of meetings over the next several months, and in terms of a timeline, the final public comment vetted report will go to Congress in March of 2015.

I want to celebrate the arrival of Jean Slutsky. I think, actually, because we haven’t had a public meeting since November, this is one more opportunity to let the community know that our
previous chief officer for engagement, Anne Beal, notified us in February that she would be resigning as of March 1st and moving on to a critical job with Sanofi Pharmaceuticals as vice-president for patient engagement. So, patient engagement is rapidly making its way into industry. That’s good. And we will look forward to a lot of opportunities to work with Anne in her new role.

Jean Slutsky was coming on as the program director for communications and dissemination research about that time and we subsequently determined that she -- it would be ideal for Jean to take on the role that Anne had held and lead engagement. Her title is chief engagement and dissemination officer. Everyone knows Jean, everyone on the Board and the Methodology Committee knows Jean because she’s been with us since the very beginning in her role at the Agency for Healthcare Research and Quality.

Everyone in the comparative effectiveness and patient-centered outcomes research community
knows Jean because she’s been at AHRQ for 12 or 13
or 20 years -- I’m sorry, Jean, I can’t quite
remember -- quite a while, and she’s really been
the face of comparative effectiveness research and
the brains behind it. So, we are very fortunate to
have Jean and you will hear from her later today
with her eight-week assessment of engagement and
how it fits into PCORI’s agenda, and I just want to
say that we are heartened and strengthened by her
addition and it’s really a pleasure to have her on
the team.

And lastly, I just want to preview today’s
agenda. Most people know that we have, through a
governance review process, we’ve reorganized the
Board into three strategy committees aligned with
our three strategic goals, to produce useful
research, that’s the Scientific Oversight
Committee, or SOC, to speed implementation, that is
the Engagement, Dissemination and Implementation
Committee, or EDIC, and to influence research by
others to become more patient-centered, to
basically transform research funded by us and others to be more patient-centered, and that is the work of the Research Transformation Committee, RTC.

And so, we will move forward with a lot of work being done in these committees and coming to the Board in the service of our strategic plan.

Today we’re going to see an agenda that is a bit of an evolution, just a transition in a direction that the governance report felt we should go, and that is that the Board, among other things, should become -- perform more of a monitoring function, to monitor the performance, how we’re doing with respect to our strategic plan and with respect to the directions we want to go.

So, you will hear for the first time today, our new dashboard, the dashboard that we think we’ll be living with for months and years to come, which I do have a lot of suggestions for changes, additions, subtractions from the dashboard, but this dashboard begins to show a longitudinal picture of our progress over time.
You will also hear a report from Dr. Romana Hasnain-Wynia on our research portfolio. The Board has asked, on a number of occasions, for more detail on what we funded, and we have been busy synthesizing what we’ve funded and Romana is going to show you the results of that effort in one program and then at all subsequent Board meetings, telephone calls, and face-to-face meetings, we will be presenting parts of our research portfolio for your suggestions and input. That’s a good way to begin identifying gaps in what we’re funding and also to get to know what we’re funding and to celebrate some of the projects that we’re particularly pleased with.

Also in the area of monitoring performance, we’re going to hear a report from Regina Yan on our five-month into 2014 financial review.

There’s also a lot of areas in which the Board has asked us about how we’re doing something or asked us to produce documentation on aspects of
our process. So, you’re going to hear three reports today from Bryan Luce, our chief science officer, on ensuring adherence to methodology standards, an issue brought up as early as last December. How do we make sure that our funded research follows the methodology standards? How do we select awards? Following the merit review and the presentation to PCORI’s board of ranked results, how do we select the actual awards that will be funded? And do we ever deviate from the ranked scores? So, you’ll hear a report on that procedure.

And the third is, how do we select research topics that come from stakeholders, that pass reviews by our advisory panels, and ultimately either get selected for targeted funding announcements, perhaps get put on the list for pragmatic -- large pragmatic studies, and what are the details of that process -- that most important process of how we set our agenda?

We’ll also hear from the Methodology
Committee on the really rather large body of work that they’ve taken up in the last few months, 2014 going forward.

And lastly, in terms of strategy, you’re going to hear a report from Michele Orza on our evaluation plan worked out in collaboration with our evaluation group. This is really our opportunity to make sure that we’ve got markers that assure us and the outside world that we are moving forward toward our strategic goals. And you will also hear the engagement update from Jean.

So, that is it, Gray, and I’ll ask you if there are comments from the Board.

CHAIRMAN NORQUIST: When I introduced you, you were supposed to make some initial comments and you went running on, so we didn’t get a chance to approve the minutes.

[Laughter.]

CHAIRMAN NORQUIST: I just let you go. You were so excited with your presentation --

DR. SELBY: I was really keyed up.
CHAIRMAN NORQUIST: -- I just let you go.

So, unfortunately, I need to just -- but we need to
back up just a second. Joe went tearing into this.
I need to get the minutes from the last meeting
approved. So, I need a motion and a second.

UNIDENTIFIED: So moved.

UNIDENTIFIED: Second [off microphone].

CHAIRMAN NORQUIST: Okay. All in favor?

[Chorus of ayes.]

CHAIRMAN NORQUIST: Anybody opposed?

[No response.]

CHAIRMAN NORQUIST: Okay, now.

DR. SELBY: Sorry about that. So, do we
have some time for comments? Good. I presented a
lot, everything from PCORNet and the pragmatic
clinical studies to --

CHAIRMAN NORQUIST: According to our
schedule we have 15 minutes for discussion here.

Yes, Harlan.

MR. KRAMHOLZ: Joe, I just --

CHAIRMAN NORQUIST: Sorry, you need to say
your name so people will know --

MR. KRUMHOLZ: Sorry about that. Harlan Krumholz. Joe, it’s a breathtaking amount of work you did for a very short period of time. For people who are listening and are very interested in what’s going on with PCORNet, which I know many of us on the Board feel is one of our most important initiatives with respect to something that might have a long legacy, what do you think people can expect to see in the next six months from PCORNet as they are sort of tracking this? And for those who are listening and are interested in PCORNet but are not part of the PCORNet network, how can they best keep up with the kind of discussions and decisions and issues that are coming up for PCORNet so that there can be some opting for alignment? And if they’re not in PCORNet, the final thing is, will there be an opportunity in the future for them perhaps to be able to interact with this network?

DR. SELBY: Thanks, Harlan. I think the best way to track PCORNet is through our website.
You saw all those taskforces on the right, and those are charged with developing white papers and policies that will go to the steering committee, and I think all of this will be done very much in the open.

A lot of this is transformative work, crucial questions about how a network like this actually governs itself and makes decisions with patient and clinician and health system input. So, a lot of excitement on that front.

I think there’s nothing as important as the issue of privacy and I think you’ll be seeing - - in the next week you’ll be seeing new material on our website related to privacy.

And I think -- I predict that you will see quite a bit on privacy including possibly even convening a meeting of stakeholders to discuss this issue.

The challenge -- the opportunity, I’ll call it, actually, of having this discussion about the value of the research, the issues related to
data security and patient privacy, and how best to engage the millions of patients whose data are available to be used, how to engage them into -- in the discussion about the uses of those data and privacy is -- internationally it’s a huge issue and it’s certainly an issue here.

In terms of the last part of your question about others, I did say that phase two is going to be open competitively to others who would like to join and one of our taskforces is actually charged with creating a data model that’s easy to interact, interface with and so I think that, you know, the message is we would love to expand PCORNet, larger than it is.

This is the only network that’s dedicated broadly to a broad range of research. This is not a disease-specific network, that is. So, we would love to become the national network at that level and that creates, then, a foundation, I think, for registries and a wide range of other applications.

CHAIRMAN NORQUIST: Francis.
DR. COLLINS: Francis Collins, Board member. I share Harlan’s enthusiasm for what PCORNet can be and how important it is to make sure we’re hearing from as many different quarters as possible in designing this and implementing it in a way that both respects patient privacy and allows research to go forward that would potentially not be possible in any other way and the power of this to be able to carry out observational studies in a relatively short term at relatively low cost is one of the things that we are particularly compelled by. But ultimately, of course, interventional studies as the gold standard, must also be a major part of the plan.

I actually wanted to raise a question about the pragmatic trials which I’m also very excited about seeing emerge out of PCORI’s portfolio and the topics that you have shared with us all look to be extremely interesting ones. One of the challenges, though, of course, is to look at the whole landscape and try to figure
out what’s already going on in terms of other studies on similar or identical problems, and that’s always been a bit of a challenge for PCORI in trying to make decisions about where to invest dollars.

So, can you say something about how that part of the process might work as these pragmatic clinical trial proposals are being reviewed? What’s the arm of the review that is going to survey what’s already happening in terms of other related research enterprises to make sure that PCORI’s investments are going to fill a niche and not pile on top of something that’s already going on?

DR. SELBY: Thanks, Francis. So, this is a process that we’ve had to put in place several times before for the targeted funding announcements, and we turn first to our Board partners, NIH and AHRQ, because they have a good handle on what’s going on.

I think there’s probably more work to do.
One of the things I think that we’re going to rely on is the inclusion of key groups that are actually knowledgeable about this on the research teams of the winners. In other words, applicants must bring along -- if this is an orthopedics question, let’s just say, for example, it’s a question about back pain, we would expect that a national organization representing orthopedists would be in sight and would be saying, look, this is the question that needs to be answered.

So, we think we’ve helped our cause a bit by requiring that people who are already in the know say this is the important question, this is the one that would help change practice, but I think, you know, a part that we probably need to work on during that same period that we’re consulting with NIH and AHRQ is consulting with industry sponsors, at least in some of the instances.

DR. JESSE: So back to --

CHAIRMAN NORQUIST: You need to say who
you are.

DR. JESSE: Bob Jesse. Board. Back to PCORNet. You know, one of the real issues here is, of course, all the privacy things that center around enrollment and the like and apropos to some discussions I’ve been having about the rewriting of the common role, I would think that as we are setting this up, we would be able to learn an awful lot about how that might be better handled in the way that we can both ensure patients’ privacy, but also liberate the ability to do the kind of research we want to do. And we had talked earlier about PCORI as a convening force. I think there’s a real opportunity to learn a lot as PCORNet rolls out and to use that to drive those discussions about how we can fix, if you will, research in this country.

DR. SELBY: Yeah, I think that’s an excellent point and I hear it. We will definitely take that back to our coordinating center and to staff, and I think you can expect to see something
in that line soon.

CHAIRMAN NORQUIST: Yeah, Allen.

DR. DOUMA: Again, I’m a very strong supporter --

CHAIRMAN NORQUIST: And you are?

DR. DOUMA: Allen Douma. I’m a very strong supporter of PCORNet and all of its potential, but it’s because it is so broad and diverse and it’s taking on challenges that others have been attempting to deal with for decades, literally, in particular the last decade, the HIEs have been enmeshed in this throughout the country. We need to be really clever and quick and so I think it’s just important that we have an organizational or governance structure for PCORNet that draws on the talents of the rest of PCORI and the people we don’t know that the RTC will be taking this up in a big way tomorrow afternoon. I look forward to the movement along those lines.

DR. SELBY: It just gives me the opportunity to say, yes, one of our three strategy
committees, the Research Transformation Committee chaired by Dr. Lewis-Hall, had this as really one of its central foci and they already have been very helpful in these discussions about PCORNet and will be working with us closely, especially on this issue of phase two -- the phase two funding announcement.

CHAIRMAN NORQUIST: Okay, so, why don’t we go ahead -- we’re about five minutes early, but we can -- Bryan, if you want to come on up.

Bryan Luce is the chief science officer. He’s going to give us an update on science processes. It’s not just -- so, it’s going to be -- I can’t see now -- implementing the methodology standards, the award selection, and the topic selection.

And, Christine, this is primarily coming out of SOC, so we’ll allow Christine to have input also if she needs to.

MR. LUCE: Well, thank you very much. I’m delighted to be here this morning. I’m going to be
talking about the three issues that have been of
deep interest and concern of the Board in terms of
the process in which we develop topics and that we
monitor the research, the methodological assurance,
and so forth.

So, I’ll get right to it. I’ll start off
with the entire process of implementing the
methodological standards, then move to the process
of award selections, and then finally go to the
topic selection process itself.

The methodology standards processes start
quite a ways back in terms of the Board’s
recommendations as to how that should go about. I
will give you a sense of that timeline. We put in
place a processes to ensure that our awardees
adhere to the standards, I will talk about that.
And then speak about the training program that we
have just instituted that we’ll be rolling out over
the next few months.

Going over -- back down to the period
prior to July 2013, you may remember that the
methodology standards were recommended for all projects in cycles one through three. These recommendations were embedded in the application guidelines and the funding announcements as well as the merit review guidance.

During part of this time, of course, the methodological standards were in a draft report. In August of 2013 cycle, the adherence was required for all projects, again, that requirement was embedded in the application guidelines and the funding announcements as well as the contract language itself.

This last December we instituted a process for award adherence monitoring, both pre-award and post-award, which I will go into in a little bit more depth, and just last month we developed a pre/post-award adherence process for staff. It was more systematic.

In terms of the pre-award process, the adherence for methodological standards are reviewed on a case-by-case basis for every project and it’s
required for -- adherence is required prior to contract activation. We have developed a checklist that staff uses to track adherence. I’m going to show you a screenshot of that. That checklist is available for your review in its entirety.

We also have established a research template for applicants to highlight standards through the application process, to sort of map the actual standard with the actual part in the application. I have a screenshot for that as well for you to look at.

In terms of post-award, adherence is monitored through the active portfolio management process we’ve put in place. We have -- we require milestones at either six months or one year, interim reports depending on the nature of the study, and of course the final report includes progress and the adherence to the methodological standards.

So, here is a screenshot of the methodology standards checklist that staff uses at
the point at which the contract is literally negotiated. You can see on the left hand side the very first standards of formulating research questions. I draw your attention to that very first item, RQ1, identify gaps in the evidence. When we look at the screenshot for the research strategy template that the applicants actually use, you can see RQ1 and all of the other standards circled there to give you an indication that when the applicant goes through the process of developing proposals that -- each section of the application is identified exactly which standard they are to review and ensure adherence.

Also want to note that in August -- for the August 2014 cycle that were awarded and -- the projects were awarded this last December, all 53 projects were reviewed by staff using the adherence review process and all methodological issues required modification were dealt with, successfully resolved and added to the milestone schedules. That was, if you recall, during our last in-person
meeting. There was a specific concern and we’ve put that into place.

In terms of next steps, we are moving back toward looking at the projects that were funded prior to the August cycle when the standards were recommended but not required and we’re going to systematically go back and check those projects for adherence, and we’ve instituted a training program that I’ll talk about next.

So, the -- we’ve been -- last year we engaged a scientific expert to help us develop a curriculum and that is in place, in part, we’ve already begun training patients and stakeholder reviewers. That started in March. The staff will be trained starting this month and then, as you can see, we’ll be rolling out the training. All this training is very consistent with the one slightly tailored to the students or the folks that we’re training. In July we’ll be training the technical reviewers, in September the prospective applicants, and then for more the general public we’re planning
a future in-person training conferences.

So, that’s fairly well developed and on the way.

So, with that -- so, that’s the methodology standards. Before we open up for questions and comments, Robin, do you have anything that you may want to add?

MS. NEWHOUSE: No, except that on behalf of the Methodology Committee, we thank you for all of your work and I know Stanley [unintelligible] has briefed us and presented us with some of the implementation strategies and we’re all very appreciative of your work and support.

CHAIRMAN NORQUIST: Okay, so, let’s -- we’ll open it up now for discussion. Did you have anybody else you wanted to recognize?

MR. LUCE: No.

CHAIRMAN NORQUIST: Okay. Well, let me just ask one question. Sharon is first, then Kerry and we’ll go around. When you’re saying that you’re requiring them to hold to the methodology
standards, and one of the things, Robin, we had had -- by the way, this is Gray Norquist talking -- if we -- if someone -- there’s some methods that you guys are proposing, but obviously there may be some disagreement in the field about what method to use. So, if someone makes a very strong case for some other method than what might be recommended by the methodology standard, that of course would be, I assume, taken into consideration, we wouldn’t be rigid about it right?

MS. NEWHOUSE: From our perspective, innovative methods should not be discouraged, but there has to be some rationale for the methods that are proposed.

MR. LUCE: Yes. That is how staff is handling it.

CHAIRMAN NORQUIST: But let me -- I just -- I’m sorry, to be a little bit more concrete about this, but on the process, then, someone proposes “an innovative method”. How is that adjudicated, whether it is indeed? I mean, who’s making that
decision that that’s okay? Does that go to the peer review? Are we having a separate group make that?

MS. NEWHOUSE: This is Robin Newhouse. The Methodology Committee has not adjudicated any disagreements, so I’m going to defer to Bryan.

MR. LUCE: There’s a whole series of processes, of course, here. Obviously, we go through the merit review process itself and these standards are reviewed at that point and then staff follow up with that. And part of the answer, certainly with respect to clinical trials, will reside with the Clinical Trial Advisory Panel that we just convened this past week that will get directly involved with both, as I think Joe mentioned earlier, the LOI process all the way through the merit review and ultimately the implementation of the beginning of the study itself.

So, the other comment I’d make is that as Robin would attest to, I think you all know, these
standards are minimal standards to begin with.

They're really not anywhere near ceiling standards and we encourage experimentation and pushing the envelope with respect to the standards.

CHAIRMAN NORQUIST: Yeah, my main thing is -- I'm assuming I'm an investigator coming in, I get dinged, I don't get my grant now, and I mean, so obviously we let them come back and I think we just need to be very clear about what was not right in that particular application and give them some instruction so that when they come back they might be more successful. They may miss it the first time if they don't get it.

Okay. Sharon, let me stop talking. Is that your question? Okay. I think, Kerry, you were up, if I remember, first.

MR. BARNETT: Just briefly. Do we require in the award contract itself that they follow the methodological standards?

MR. LUCE: That's correct.

MR. BARNETT: And so then if we were to do
our review a year or two later, during the research trial itself, and find that they’ve strayed from those standards, that would provide some very specific recourse for us. Is that the idea?

MR. LUCE: That would legally be the case, that’s exactly right. The staff have really put in place a fairly rigorous monitoring process, so, you know, presumably that will be picked up as things go along, but, you know, research goes astray and so I expect there will be issues coming from time-to-time.

CHAIRMAN NORQUIST: Harlan and then I think it’s Francis and then Harlan Krumholz.

DR. WEISMAN: You know, one question I have tying this back to PCORNet and the availability of vast amounts of clinical information, Francis talked about the ability to do outcomes research outside the setting of an RCT. Now, methods are available for doing this. These are often controversial in terms of those methods, and I think one of the bullets talked about
Bayesian methods.

How much of this is coming up and are we -- maybe this is more of a question for Robin -- what -- all these things are brought up and it’s contrary to the methodologic standards, which set a base of providing information about the methods being used, but how much are we exploring, either through the grants that are being sent to us or by solicitation of grants to look at methods of outcomes research outside the setting of -- you know, more in the setting of real world observational data?

MR. LUCE: Well, in the course of the actual applications up to now, we haven’t specifically faced that although a lot of these projects, of course, are being conducted in real world settings. I mean, that’s sort of the nature of what PCORI has put in place requiring stakeholders to be part of the process and part of the project and the project team as well as patients and patient advocates and so forth.
You raise a really important point. It's actually the subject of a session we're going to have at academy health, specifically focused around the application of pragmatic clinical trials within a learning healthcare system like PCORNet and we're literally going to tee all of that up and start thinking through how it really works in that kind of setting.

I think there's a long way to go and a lot of methodological issues that will be grappled with as real world research is done within a real world operating system that needs information to make decisions about healthcare as well as, you know, the research findings themselves.

DR. WEISMAN: You know, I asked Joe, it seems at least until now, almost all, if not all, the pragmatic trials that we will be -- that we're looking at are RCTs, and nothing wrong with that, and I think everybody supports that, but there is the limitation on how many questions can be asked by RCTs from a funding -- just from a pragmatic
standpoint, just how many pragmatic trials --

MR. LUCE: Right.

DR. WEISMAN: -- you can do, but observational studies are much less constrained in that way and I think a lot of times they’re written off as mere anecdotal information when, in fact, looking at them and looking at them in some systematic fashion allows you to use information that is sitting there otherwise and not being utilized.

MR. LUCE: Well, that is absolutely in our plans and even the list that Joe showed of the topics that we’re expecting, that we’ve invited to be -- to come in for this particular solicitation, that will include, and I’m sure it does include, observational studies.

So, we’re trying to point toward randomized trials in real world settings, that is sort of pragmatic, different degrees, of course, depending on the issue, but it also includes observational studies and certainly I see, I know
as staff sees, I’m sure you all see, that the
decisions that need to be based on evidence will
include all evidence, that coming out of non-
randomized observational data as well -- some of it
more systematic than others and others being from
randomized trials that may be very, very well
controlled and others much less so controlled
depending on the issue.

There’s an awful lot of room to move here,
which provides a lot of opportunity and a lot of
challenges as well.

CHAIRMAN NORQUIST: Harlan Krumholz.

MR. KRUMHOLZ: I wanted to raise two
questions, one easier and one a little bit harder.
I’ll do the easier one first.

What a tremendous advance, a great tribute
to the Methodology Committee and the way in which
the staff have worked together with them to
implement these policies. I think they’re
tremendous. They ought to be quite visible in
terms of how grants are conforming with this
because part of this is around the spread and the
changing culture and the normative thinking about
that. In that line I totally salute the
curriculum. You know, we talked about this in a
prior meeting and it’s wonderful to see that moving
forward.

I was looking on the site, saw the
wonderful video of Robin prominently displayed on
the methodology page, but what I really would love
to see now, not when we get the curriculum, but
now, is a toolkit because I’d love to use this in
my curriculum tomorrow.

Like, when I’m teaching people how to do
grants or thinking about projects, when I’m telling
them to make proposals to us, talking about
anything from medical students on up, I’d like to
hand them this toolkit and say, I want to crosswalk
what you just gave me to the standards that the
Methodology Committee has put out.

And I think far in advance of having any
sort of sophisticated curriculum, the tools that
you’ve already created, by which you’re already evaluating the grants, can be -- I can use them tomorrow and they’d be so beneficial to me. And not only that, I’m doing work in other countries, as many of you know, and many people are at much earlier stages of their scientific development, and to be able to give them these documents, translating them into their languages and helping them to see the kind of construct and framework by which these sort of proposals are put together would be tremendous. It would also spread the word of the work that has been done and pay honor to it.

So, that’s the first thing. That’s the easy one. Do you want --

MR. LUCE: Yes. We are highly supportive of that and I think the training modules will help.

MR. KRUMHOLZ: I'm even saying, even before you get to the -- finish the final versions, I want an alpha version that I can just take tomorrow.

MS. NEWHOUSE: Well, and I would just say,
many inter-professional colleagues are asking for the same thing, just cases, exercises, how to apply the methodology report, just some suggestions for how to incorporate it into their teaching. So, I’ve seen an exponential increase in the request or they ask me if I have anything like that that I’m using.

So, I will second that.

MR. KRUMHOLZ: In the spirit of that, just on the website, make it really easy for me to find it. So, if it could be like a little box there that says “go here for Methodology Committee tools” or toolkit or something like that, because sometimes when I get to the site it’s so packed with information. You guys have done a great job filling it with so much knowledge, but things like this people just want to be able to, bang, get to. It’s good advertisement for us. It should be really easy. And there might even be a shortcut URL, just PCORI toolkit.

MR. LUCE: Harlan, we actually developed a
checklist for the field, which is very similar to the checklist, I showed you that one screenshot, but the feeling of the staff was that we weren’t ready to roll that out, we didn’t want to confuse – we thought it was too confusing until we went to a training program.

But we’re pretty close to where I think you want to go and I’m certainly supportive of that.

MR. KRUMHOLZ: And be glad to call it version 1.0, because, I mean, I think this is going to iteratively evolve anyway and, you know, so then, just don’t let perfect be the enemy of the good, that’s all, because what I’m seeing here, I could use, and I think a lot of other people could too.

The second thing I just wanted to jump into was this issue about the pragmatic trials and, again, salute you at the pace with which you were able to take what were ideas that were floating around here and elsewhere and get them into a call
and evaluation. So, I think that’s terrific.

I just want to add one other dimension here that I think is really important, which is, our goal is not only to produce great science and science that can be used, but we also want to try to improve the research enterprise. And in that spirit, you know, we’re trying to figure out how to do research faster, better, cheaper and PCORNet’s part of that, but in every aspect of these pragmatic trials, we ought to also be evaluating, you know, what’s the price-per-subject? How is that price benchmark?

And are there innovative aspects to this that would allow us to generalize it? Is it going to be sustainable or is it going to be built up and then dismantled? I mean, all of these particular pieces -- it may be too late for the first call because we don’t want to change the rules for people who have applied, but as we think forward, I think what we’re trying to figure out is how does this fit in.
And in alignment with that I wanted to ask you the question, which is, if we thought there was a great question but that the way in which it’s being proposed is overpriced for what it could be done, would we be willing to say, we want to do that project, but we want to see if we can do it for half the price? And so we’d like you to lead it, but we want to now go out and competitively bid because you guys are quoting us a price $1,000-per-patient.

We want to see if it can be done for $250. We want to see if it can be done for $150. And we want to see what kind of creative ways either leveraging PCORNet or others. And so then we are a catalyst for not only just saying, we want the great ideas, but we want the innovative solutions to how the research is conducted and we want to figure out whether we can change the way that people have assumed it must be done in the past in order to get it done.

When I heard Harlan Weisman say, well, you
know, the trials, they’re just too expensive and
you just can’t do to many of them, I want to
challenge us to say, well, let’s think about how we
can do experiments.

What I’m seeing in industries outside of
medicine are people saying, we need an experimental
culture. We need to be able to build this into the
way that we do our work everyday. We need to
recognize that there are questions for which we’re
not sure and we’re bound by limited resources, so
we have to do phase-ins with regard to how we’re
doing our work. Well, set it up as an experiment.
Now we’ve got to work on the privacy, consent,
there’s lots of issues here to deal with, but I
think we should be challenging people who are
applying to us to get that price point down so
that, you know, and this makes a big difference
because we may be able to do twice as many studies
if we can get the price point down on each of the
trials that we are doing.

So, this has tangible impact on every
patient around the country because if we can only –
- you know, we want to expand the capacity with
what we can do with the money that we have on hand
as much as possible.

So, I’m just curious of your thoughts
about that.

MR. LUCE: Well, we’ve thought about it
methodologically a little bit and that is this
methodological consultation service that we spoke
to the Clinical Trial Advisory Panel just last
Wednesday and I know the Methodology Committee has
done some speaking about it and we haven’t put it
into place yet, but the thinking definitely is, you
know, from just the methodological standpoint, how
we can intervene in a very positive way to improve
designs. You’re getting into a whole new
dimension, obviously, and actually if you don’t
mind, Francis, I’d love to turn to you because the
NIH has just gone out, what, about three, four
months ago, with a pragmatic trial announcement
that drastically lowered the price-per-trial, at
least in the announcement, and it will be very
interesting to see whether, in fact, trials can be
done at that -- good trials can be done at that
price, in essence.

How you put that into play, I don’t know
exactly in terms of revising a study and
negotiating with particular study applicants in
terms of totally changing the nature and how they
go about doing it from an economic standpoint, to
the point you’re talking about, but I think there’s
a lot to learn that we will learn ourselves and I
think that the NIH will learn and help us move
forward on that.

DR. COLLINS: So, if possible I would like
to call on Mike Lauer to answer that question
because he can do so with greater specificity than
I can.

DR. LAUER: Thanks, Bryan. This is music
to our ears. So, a couple things, one is a
collaboratory -- the Common Fund Collaboratory has
already been working on this and we’re already
funding a number of trials at less than a million dollars a year in direct costs and what they’re doing is they’re leveraging existing resources and through the same folks who are helping to work on PCORNet, we’re converting this into a learning experience, so this will help us further on down the line.

Secondly, we’re doing this, and I’ll tell one real quick, 30-second story. I had a group of investigators come in with a trial, an interesting CER trial where they wanted $10,000 per patient and we pointed out to them that they had access to resources that would make it possible for them to collect 90 percent of the data that they needed, high quality, at essentially no cost. It was right under their noses and they hadn’t even thought about that.

So, then they circled around and came back with a proposal, which was about 25 percent the cost of the original one.

So, this is -- the realities of the
current budget are creating great opportunities for us to, in a way, force people to become resourceful.

DR. COLLINS: Okay, thanks.

MR. LUCE: -- how we can use our colleagues and collaborators to -- kind of a learning healthcare system, a learning research system, and presumably, this is what PCORNNet will allow us.

CHAIRMAN NORQUIST: Okay. We’re going to need to move on. Go ahead, Harlan.

MR. KRUMHOLZ: And just one other thing I would ask is in the spirit of transparency, why don’t we take our trials and show what the price-per-subject is and publicly report it so that people can see what it is. I think that will put pressure on us and also show the world sort of what we’re investing in and give a -- it will put focus on the value of information that’s been gained from that.

CHAIRMAN NORQUIST: Freda, did you have a
comment?

DR. LEWIS-HALL:  Um --

MR. KRUMHOLZ:  You're not going to say yes on that, Gray?  You’re the chair.

CHAIRMAN NORQUIST:  It’s the Board’s decision, not mine alone.  I’m waiting for everybody else to vote.

UNIDENTIFIED:  So moved.

CHAIRMAN NORQUIST:  Allen -- two people -- We wouldn’t take a vote.  I think Mary wouldn't allow us to take a vote on that at this point.  I know we’re just kidding.  We’re having a good -- but as a general idea, I don’t -- look, let me just say, when I was at NIH, we had the same kind of struggles and we pointed out to people quite often, look, the game, if you’re sitting on the other side sometimes is you want more money because that looks very prestigious, all this stuff, you know.

I think, Harlan, you’re absolutely on point here because it may be that we start to develop a cadre of people who are kind of the
operations arm for trials and you have other people
who sit, so if we had this, so then we can have our
own infrastructure in which we can operate these
and the ideas come into play on that. That’s the
whole idea of infrastructure, but I think it’s
pretty clear the price points are vastly different
and not always for rational reasons.

So, I’ll say that publicly. Okay, Freda.

DR. LEWIS-HALL: So, my quick question
goes back to an earlier point that Harlan made and
that is, do we have any ability to capture how the
methodology is changing not only through our
assessments or PCORI-related grants, but is there a
way to kind of take some kind of assessments or
metrics around how we’re shape shifting the more
general research community with the methodology
report?

MS. NEWHOUSE: I would say Michele will be
presenting the evaluation plan and I think we’ll
address some of those answers. Yes, there are ways
to understand are these standards being, first of
all, endorsed, second of all, adopted, and third, used.

CHAIRMAN NORQUIST: So, is this going to be quick? Because he’s got two more topics and we need to move.

DR. DOUMA: Allen Douma. I’d also like to add to that list that we need to begin tracking now what are the outcomes that are improved as a result of adopting the methodology report?

CHAIRMAN NORQUIST: Yeah, okay. And I do want to pick up on Harlan Krumholz’s earlier point about the training stuff, because we’re all being asked -- I’m being asked this all the time, I’d love to have these. And there’s no reason -- and I’d like to see us not just say it’s a good idea, but let’s pick a deadline and let’s do something here and get it out, okay? So, you don’t have to answer right now, but let’s just have that as a process.

MR. LUCE: Agreed.

CHAIRMAN NORQUIST: Thanks. All right.
What’s your next topic here? Award Selection?

MR. LUCE: Award Selection process. This is pretty well established, I think. Now, you’ve all seen this circle, we’ve re-titled it a little bit, but this just goes from upper left, PFA development through letter of intent all the way through the application process and the merit review to the final Board of Governors funding slate review. So, I won’t dwell on this by any means, but I wanted to talk through and just make it very clear to you and to the public how we go about establishing this funding slate.

The top scoring applications that come out of the merit review process are reviewed by the program directors. The initial funding line is set based on the available program funding and application budgets. That’s been true all along. The applications are reviewed for any budget adjustments that are required. This goes, in some ways, to what Harlan was just talking about.

Staff recommends a slate based on merit
scores and exception criteria. The default is always on the merit scores. There are specific issues that staff may bring up on a given project relative to exceptions, and I’ll get to that in a minute.

A slate has been submitted to the selection committee for review and approval and the selection committee brings it to the Board for final approval. You’re all aware of that.

The exceptions criteria has been put in place that are outlined as before you. There has to be a fit with programmatic vision as outlined in each strategic framework, for each program. The potential synergy within the portfolio, avoiding duplication in project aims within the portfolio and possible adjustments to address between panel scoring differences.

So, these are the types of exceptions that can occur where staff would recommend changing the mix in terms of what would be considered for funding.
The guidelines for recommending the projects are as follows: in addition to the merit review scores, which again are the defaults -- I mean, if the staff agrees with the merit review scores, that goes directly for consideration for funding.

But the projects that are discussed based on the exception criteria I just talked about, those applications go to the Selection Committee members who will review both the abstract and the summary statements of all such recommended projects that are exceptions based on the considerations other than the merit review scores and in selected cases the selection committee may request the entire application process. You recall that the selection committee is made up of Board members mainly and Methodology Committee members.

And I just want to make note that the award selection process was reviewed by the Science Oversight Committee and all of their recommendations were incorporated.
So, that is just quickly where we are on that. I think we’re ready to -- I think this is pretty much put to bed. Christine, you may have comments.

CHAIRMAN NORQUIST: So, let’s let Christine as chair of that committee have some comments here.

MS. GOERTZ: Thank you. Christine Goertz. Thank you, Bryan. Just a reminder that this is one of the topics that we discussed during our retreat in February and the SOC has been working with staff in order to finalize this SOP and it’s sort of, you know, hot off the press, actually, the final version, and so we can make sure that Board members have an opportunity to take a look at that before it gets, you know, posted publicly or however it is we’re going to handle this particular SOP. But I just want to thank Bryan and the staff for putting this together because it’s been -- it’s always an interesting process when you have a process in place but then when you go and try to write down
the criteria and try to figure out how to
standardize a process that does not easily fall --
it’s not easily standardized, it can be complicated
and they’ve just done a great job.

CHAIRMAN NORQUIST: So, can we come to an
agreement on when this will be finalized, when it
will be ready and stuff so that we can --

MS. GOERTZ: I think the SOC will be
looking at it for a final time tomorrow. Is that
correct, Bryan?

MR. LUCE: Absolutely.

MS. GOERTZ: So, it will be tomorrow
afternoon at 3:00.

CHAIRMAN NORQUIST: So, by the next Board
conference call we could probably have this ready
to vote on, is that right?

MR. LUCE: We’re not --

CHAIRMAN NORQUIST: It doesn’t need a
vote, but agreement. Agreement that this is the
process. Is that the plan? I mean, you’re saying
-- what is the plan at this moment?
MS. GOERTZ: Yeah, I think, the SOC is working with staff to develop SOPs in several critical areas related to our science portfolio, so our plan is to post the SOPs somewhere so that -- and to let Board members know that they’re available so that instead of having the -- because we will spend all of our time looking at SOPs if we start bringing them to the Board.

CHAIRMAN NORQUIST: Okay, so, that’s what I wanted to get at is the process here. So, what you would like, basically, for us to agree on, which we could just basically agree on, is that the SOC will do the majority of the work. We will kind of empower you to develop these SOPs and then we’re certainly free, as Board members, to look at those and have input or something, but we don’t need to formally bring them back all the time to move it forward, is what you’re saying?

MS. GOERTZ: Right. As SOPs are developed, we will let the Board know that they have been developed and how to access those so that
the Board has an opportunity to take a look at them and make further comments.

CHAIRMAN NORQUIST: Okay, so I just --

MS. GOERTZ: But there won’t be a formal approval process.

CHAIRMAN NORQUIST: Great. So, I then we just all agree on that is what -- I just want to come to that decision. All right --

MS. GOERTZ: That’s what the SOC is recommending to the Board.

CHAIRMAN NORQUIST: Okay, so, does anybody have a disagreement or not like that process, I guess is the question, right?

[No response.]

CHAIRMAN NORQUIST: Good. Okay, so you’re empowered to do this but you do need to -- you guys need to put it up so that we can all see and be very transparent about what that is, okay? But I would ask that -- the only thing I would say is, do these, do them quickly so you have a process, because the worst thing is that if you’re an
investigator coming in and the selection process changes every time or we’re unsure what it is, that’s not what you want. Okay?

All right, yes, it looks like, Alicia, you want to say something, but our little thing is we put our cards -- we turn our cards. All right, thank you.

DR. FERNANDEZ: Thank you. This is Alicia Fernandez. I just wanted to be sure that I understood whether you were suggesting that these be posted as is in terms of the boarding cycle. Let me just tell you, perhaps it will be more helpful if I explain my concern, which is that obviously the scientific community which has concerns about exceptions because of the difficulties as it is of navigating a rigorous -- appropriately rigorous peer review process and I wonder whether there should be some language in there around -- and perhaps this is something that is best discussed in committee, but I’m wondering whether there should be some language in there...
around the limitations of exceptions or around how exceptions, around which -- under which criteria, for example, an exception is made, for example, duplicative of an existing study or so on and so forth.

Only, again, to be reassuring to the scientific community that exceptions are rare, they are important, they highlight the work of the entire scientific community and the research agenda, and so on.

But again, this is something that may be best considered in a committee discussion as I’m sure there are lots of nuances that I’ve failed to consider.

CHAIRMAN NORQUIST: I think it’s critical and I think it’s part of what we always want to say in an award criteria that, you know, we have the authority to not pick because of certain things like this is duplicative or something, but I think, Christine, you might want to --

MS. GOERTZ: Thank you for that comment
and now that you’re coming on board and will be a member of the Scientific Oversight Committee, you’ll definitely have a lot of opportunity to be a part of that process and, you know, Bryan and I have been in a lot of discussion about this and this is one of those SOPs that we feel absolutely needs to be, you know, made public and that our investigators need to be very aware of how the selection process occurs and when exceptions might happen and what those will look like.

So, again, once this SOP is finalized, we’ll be looking at ways to make sure that people are educated about it so that they’re able to know how the process works.

DR. DOUMA: Allen Douma. Just to reinforce what we just heard, also would be helpful, and maybe you can quickly do that now, to re-acquaint me with how is -- what is the selection committee? How is it chosen? Whom do we try to put on that committee in order to be able to maximize their ability to make exceptions?
MR. LUCE: That's a Board decision and I'm not -- Joe or --

CHAIRMAN NORQUIST: No, there's a

selection committee. We don't just --

DR. SELBY: I think up to this point we have solicited interest. We're working carefully, particularly now as the selection process begins to look at more of the information about particular studies to place a conflict of interest review at the beginning of it and the other principle that has been held to since the beginning is that we rotate that responsibility over time so that all Board members ultimately participate in the selection committees.

MS. GOERTZ: One of the things that we've been in discussion with is trying to balance, you know, rotating people through with consistency and making sure that, you know, decisions that are made in one round are consistent with the other. So, that's something that we're continuing to work on.

CHAIRMAN NORQUIST: And of course
ultimately the decision about the funding comes to the full Board. This is the recommendation from the selection committee, so just keep that in mind also. Okay.

Bob. I’m sorry. I missed your card.

DR. ZWOLAK: Bob Zwolak, Board. Bryan, earlier today Joe pointed out that the GAO in their initial letter had asked us to what extent PCORI is establishing the research priorities and then funding research in accordance with the priorities and for the pragmatic trials I think that most of them are either consistent with the IOMs list or PCORI’s list or sometimes both lists and although there’s a small number, I think, that may not have been on either list.

So, having made it through the threshold from letter of intent to invitation to submit a full application, does that mean that the ones that are on neither list have shown enough value that we would still fund them? And will they be considered equally from this point on until the ones that are
on, say, one, or potentially more than one list?

MR. LUCE: The present policy is absolutely that, that proposals that come in are based strictly on the merit, not just technical merit, but merit relative to their likelihood of making a difference and importance to the field, but there’s no preconceived screen or special gate that a proposal has to go through that’s relative to what is already on an established list. But it is a very strong message to the field that paying attention to the topics that we’ve keyed up that we think are important is what we tend to get most of. But there’s no special screening.

CHAIRMAN NORQUIST: Okay. Your last topic.

MR. LUCE: Moving on to my last topic. Dear to the hearts of many here and to us is the topic selection update. This, just to tee it up a little bit, this is -- we really went back to ground zero after the Board retreat to review the entire topic selection process and we are ready to
put this to bed with the Science Oversight Committee, hopefully tomorrow. We’ll, of course, see how that works out, but I think we’ve come to the point where we have -- we’re in basic agreement.

To just give you a brief background, the Board indicated an interest in reviewing the topic selection process and its role, probably all along, but in particular I think it reached a head at the Board retreat last December. The Science Oversight committee asked us specifically to engage a process improvement expert to help us with this process, which we did do. It took a little bit longer to put in place than we had hoped, but we worked the contract folks as fast as they possibly could and the experts really moved very quickly.

The process was completed in April. The SOC has been fully briefed at their process itself and their findings and then over the past several weeks, staff has, across scientific staff and engagement staff, have vetted these recommendations
through really a formal process of a survey and reviewed the processes and now made recommendations that have gone to the Science Oversight Committee literally as we speak, right now. I’ve been in close contact with Christine, as she knows well.

So, we have both a set of recommendations and a revised SOP that will be discussed tomorrow.

Just to give you a sense as to what this expert consultant group did, it reviewed all of our existing policies. We had, really, a draft SOP of the entire topic selection process that’s been unfolding since really the beginning of PCORI, or at least the scientific staff and the advisory panels and so forth, that you’re all pretty familiar with. So, they reviewed all of the existing policies and procedures in great detail. They interviewed selected Board members and selected science staff. They depicted a detailed map of the entire topic capture and prioritization process, which turns out to be quite complex that I’ll mention in a minute.
They paid special consideration about the Board role in their process, which is really what really generated a lot of the interest in December here and then they recommended improvements.

To give you a sense of the scope of the topic capture and research prioritization process, there’s a specific SOP for each one of these, for engaging stakeholders, for monitoring, for new opportunities such as the gap analysis and discussion with other funders such as NIH or AHRQ, developing individual program strategic frameworks, which is in the process right now. You’ll actually -- you’ll get a flavor for that one when Romana speaks to you later on today, a process for capturing topics and database management that’s in process right now, a process of vetting and prioritizing topics, developing topic briefs and landscape reviews as indicated, prioritizing topics by the program advisory panels that you all are very familiar with, and refining the research questions ultimately for PCORI funding.
announcements.

So, each one of these processes have multiple steps. I think there was something like 156 individual steps. It was all put together in a very complex diagram that I won’t show you. So, there are two basic issues that really come out of this, I think, that are of key interest to the Board and to the Strategic Oversight Committee, one is the timing and the nature of Board involvement probably through, in many easy, through the Strategic Oversight Committee.

So, precisely where the Board intervenes adds input to that topic generation and prioritization process. And the other is, which also needs to get worked out, probably has to be flexible, is the extent of information that especially Board members need, but all of us need, and the advisory panel themselves need, in terms of the topic brief are full landscape reviews, are systematic evidence reviews appropriate for the actual process. There’s just a lot of scope here
because a full landscape review can take five, six or more months, cost a great deal of money, and what we’re trying to do is titrate the amount of information that’s really required for the decision to go or no go. And to whether to go into a full targeted funding announcement versus a list for pragmatic trials or in general announcements.

So, that’s what we’re doing and that’s what we’ll be talking to the SOC tomorrow about. I’ll be happy to answer any questions.

CHAIRMAN NORQUIST: Okay, let’s let --

MR. LUCE: Christine may want to --

CHAIRMAN NORQUIST: -- Christine make some comments and then the one thing that’s also missing here is the third point about the criteria for what we will use to select the topic that becomes a targeted funding announcement as to ones that are perhaps a different category.

MR. LUCE: That's right.

CHAIRMAN NORQUIST: Christine.

MS. GOERTZ: Right. Thank you, Bryan.
Christine Goertz. As Bryan has indicated, this is a very complex process and as we all know from the discussion that we had at our retreat, there are a lot of parts to it and a lot of steps in each of those parts and so we had originally hoped that we could get this -- and this particular SOP we are going to be coming back to the Board with because we do think it’s so key to what we’re doing and we are trying as hard as we can to move quickly through this process.

And so, as Bryan mentioned, our hope is that we either finalize it or get close to finalizing it at the SOC meeting tomorrow and that this would come back to the Board meeting in June so that you are able to take a look at that and have input actually looking at it in a little bit more detail with particular emphasis on those touch points where the Board, through the SOC, would get involved in the process.

CHAIRMAN NORQUIST: Yes. This is an important issue because it gets to the point of
getting these topics out, getting them funded, and
the key issues are: what are the touch points for
the Board, primarily, we’re hoping, through the
SOC, to be kind of empowered to do that, this issue
of when we need full landscape reviews and stuff?
The other thing that we agreed on is to move
earlier into the process, which I think is to get
more feedback from the funders so that we get more
experts early on in the process and certainly the
advocacy groups that are in that area so we don’t
try to push something through a process where it’s
pretty clear it’s just not going to go or it’s been
tried before. And third point is, what criteria
are we going to use to decide whether something’s
our big trial, basically, you know, a targeted
funding announcement where we put specific
resources into a specific question, versus some
other kind of mechanism we may use to cover a
topic.

So, please pay attention to this as this
comes out because we want to finalize this and get
this done because we need to get moving to get the
topics through so we can get this done.

    So, Larry I’m going to start and we’re
going to go down around, because I don’t see
anybody on this side yet, so Larry and then Sharon
and then Ellen and then Allen.

    MR. BECKER: So, I just wanted to thank
you for --

    CHAIRMAN NORQUIST: And this is Larry
Becker talking.

    MR. BECKER: I’m sorry. Larry Becker. I
just wanted to thank you for taking the time to
walk the process. We know from LeanSixSigma kind
of work that we do, when you put that process out
and you put those 150, 160 steps around the room,
you learn a lot, your partners learn a lot, the
stakeholders learn a lot, and at the end, you get a
much more efficient and effective process. So,
thank you for doing that.

    MR. LUCE: You’re welcome.

    CHAIRMAN NORQUIST: Sharon.
DR. LEVINE: So, two comments, the first is just a small process thing, but it would be helpful when you’re putting information together, rather than referring to a generic scientific science expert or process improvement expert, that you actually put the name of the individual or group that you’re using, just for informational purposes, I think it would be helpful.

MR. LUCE: Yeah. I actually agree with that.

DR. LEVINE: The second thing is, as a non-researcher in the room, I think it would be very helpful to clinicians, patients, and members of the public if somewhere on the PCORI website there was a brief description in lay terms of the different kinds of trials that PCORI funds and what the terms mean -- pragmatic clinical trials, targeted funding announcements, randomized control trials -- just a glossary of terms around different kinds of research that PCORI funds and why or what the intent is, perhaps then go into the methodology.
standards for anyone who’s interested, but some way
to demystify the inside baseball talk.

CHAIRMAN NORQUIST: We’re laughing because
we were having this very discussion last night
about the need to define these things. So,
absolutely, it’s critical. We need to define what
the game is we’re playing, right?

MS. SIGAL: Ellen Sigal, Board. So, Bryan,
thank you. I know that the outcome will be
significantly better, but, you know, the feelings
were that it’s taken a long time and we often
didn’t get to results that we could have or should
have had we engaged the Board or content experts
earlier in the process in really some landscape
reviews.

I know that we’re still voting on this and
looking at it, but can you, perhaps, summarize the
significant changes that will occur with the new
process? Because, again, the intent is to really
not spend a huge amount of time and find out that
we’re off on a tangent of work that’s already
duplicated or is not a high priority to priority or perhaps subject matter experts.

MR. LUCE: I certainly can. Is it -- so, I’m turning to Christine as well because I don’t want to preempt the SOC, but --

CHAIRMAN NORQUIST: We’ll let Christine get this and then, Bryan, you can chime in if there’s something that you missed.

MR. LUCE: Yeah.

MS. GOERTZ: Yes, thanks, Ellen.

Christine Goertz. I think that’s an excellent question and, yes, we’re definitely planning to insert the SOC and several layers of experts earlier on. So, for instance, now the plan is what has been happening is that the Board and the SOC didn’t get involved until fairly late in the process, as you know. What we’re planning to do is have the SOC involved actually before it goes to -- any of the topics go to the advisory panel.

So, not only to have the SOC, but also have it vetted by experts in NIH and AHRQ and other
-- and stakeholder groups as well so that when the
advisory panel actually looks at the topics that
are queued up, those are pieces of information that
they’ll have -- what did the stakeholder groups
say?

What’s happening at NIH and AHRQ or other
agencies related to this? What are the comments of
the SOC? So, that goes into the mix and then
trying to -- and, again, shortening the process
instead of having these lengthy and very expensive
landscape reviews, I think that would be much more
the exception than the rule.

And then the other touch point for the
Board through the SOC would be at some point you
have to decide -- you have, you know, 50 topics or
40 topics that have gone through the process and
trying to figure out what you do with all of these.
You can’t write targeted program funding
announcements for all of them, so trying to sort
them into buckets, you know, the buckets are a
targeted funding announcement, which my
recommendation is that that would be when we know exactly what the specific question is.

And so, it’s a very finite question, we’re going to do a targeted PFA or there may be times when we say, you know, we’re just going to list this as a general area of interest within our general funding announcements or we may decide to put it on the pragmatic clinical trials list or maybe some other kind of trial that wouldn’t fall under our definition of pragmatic trial. But just helping to sort out which of those buckets it goes into and then what -- is there a financial set-aside or not, because with all of those options you can either have a set-aside or not, so trying to decide, do we want this to compete -- that topic to compete against all other topics or do we want to say this is such an important topic to us that we want only -- we want to be asking people to compete within that general topic area for dollars that have been set aside?

DR. LEVINE: I think that’s really
important and of course, as we start to analyze our portfolio for gaps, this will also inform us too, this will be very much part of that.

MS. GOERTZ: And as you know, that’s one of our goals for the SOC over this year is to really do that kind of gap and opportunity analysis within the portfolio.

CHAIRMAN NORQUIST: And the other reason that we’re asking for at every Board meeting to have an update on a part of the portfolio so that we all know the portfolio, which I think is critical too.

DR. DOUMA: Allen Douma. Thank you for all the work you’ve been doing, particularly having to slog through the data diagram that you’re referring to. Having been an engineer in my past, I actually love them, so I look forward to seeing it sometime in the future.

MR. LUCE: I’d be delighted to send it to you.

DR. DOUMA: Please do. Please do. In the
spirit of what we’re hearing -- talking about
before, and Harlan Krumholz in particular having
toolkits for both external as well as internal
transparency, it’d be great to these significant
things, two of which we talked about today are
landscape review versus something else --
literature, systemic evidence, review. And the
second being determining how much research is -- if
there’s as much ongoing research we don’t want to
duplicate. What we need to have are tools that
basically use or have a set of criteria to
determine when enough other research is being done
and to determine when we do a landscape review.
So, it can be more consistent and methodological
with our methodology as we move forward.

MS. HUNT: Gail Hunt, Board. I listened
to what you said Christine and I’m saying to
myself, okay, so we’re saying that the SOC will
have prepared or will have done a lot of review in
advance before this goes to the advisory committee.
But I guess the question I have is, that’s great.
Is the advisory committee the last stop before the Board? Or is it the SOC, the advisory committee, back to the SOC and then the Board?

MS. GOERTZ: Correct.

MS. HUNT: Okay, great.

MR. LUCE: Gail, what we’re trying to do is to eliminate the process by which topics get through all of the advisory panel and then get derailed because it’s clear that there wasn’t any question that could be answered appropriately or that there was really not consensus among key stakeholders and so forth. We’re simply trying to make this process more efficient and to provide the Board, through -- especially through the SOC, more touch points earlier in the process. But we think it is going to be a much more efficient process.

CHAIRMAN NORQUIST: Okay, I don't see any other cards up. I think, Sharon, yours was left up. So, thanks. So, we are five minutes early. Let me just -- I’ll recap from the methods thing. I think the key thing there, we got an issue about getting
these training or at least getting out some of these checklists as soon as possible, I think, quickly, we have a plan hopefully soon to do that. This issue about what’s the price of our clinical trials and how to operate them, what’s the most cost effective way is something that we really need to focus on and to think about.

   On the selection process we’re going to allow the SOC to basically make it approve the SOP for this, but we’ll put it up for Board information. And then on the topic selection, because of the importance of this one we’re going to bring it back to the June Board meeting so that the Board can finalize it, but there will be a lot of work, obviously, the SOC will do in the meantime. Did I miss something? No. Okay.

   Thank you all and for those listening on the phone, we’re now going to take a break for lunch and we’ll be back at 1:00 p.m. Eastern Daylight Time. Thanks.

   [Whereupon, at 11:66 a.m., a luncheon]
AFTERNOON SESSION

[1:00 p.m.]

CHAIRMAN NORQUIST: We are going to be starting back here because we are supposed to start at 1:00. So, if people could get into their seats.

DR. SELBY: Good afternoon, everyone, if you’re in the room and on the line. This is Joe Selby, Executive Director of PCORI and we’re going to have a presentation right now from Dr. Romana Hasnain-Wynia, a synthesis of the disparities portfolio of projects that we’ve funded.

The Board has asked, and we as staff agree wholeheartedly, that we need, as an organization, to heighten our awareness of the projects that we’ve funded so that we can, among other things, identify gaps in what we’ve funded, identify consistent trends that might need to be emphasized
or supported more, and, frankly, have projects that we can talk about even as they are ongoing.

So, under Bryan Luce the Science Program has developed an active portfolio management. Now I think it’s called the Strategic Portfolio Initiative, which was first suggested by Arnie Epstein about a year ago at a board meeting. We have been very actively looking at the projects we funded, getting familiar with them and looking for patterns and overlap.

And so, Dr. Hasnain-Wynia is going to go first, as she often does, and we appreciate that and I think you’ll find this a very thoughtful presentation. We look forward to your comments.

MS. HASNAIN-WYNIA: Great. Thank you very much, Joe, and I also want to thank the Board for the opportunity to present you with an update of the Addressing Disparities Program at PCORI.

So, what I’m going to do is give you a little bit of background information. I’d like to set the presentation in this context, so just a
brief review of the program’s mission and goals.
I’ll review the program’s progress to date and then
spend a little bit of time talking about a
conceptual framework that we’ve adopted to guide
the program, and then a driver model that is really
being used by us as a tool to help us understand
where we are and where we may need to go. We’ll
have a few slides on next steps and I would really
welcome your comments and your questions.

So, I do have to acknowledge the
Addressing Disparities team. The team is a
dedicated, hard-working, fun, smart team and the
work really could not be done without them, so I’m
referring to -- not myself -- to my program
officers, Cathy Gurgol and Ayodola Anise as well as
our program associates, Katie Lewis, who’s in the
back of the room today, and Mychal Weinert.

And then Tomica Singleton, who is our
senior administrative assistant, who is represented
by the flowers versus her picture, and I should
also let you know that we are going to be bringing
on an additional program officer towards the end of this month and we’re really looking forward to that.

So, I don’t think I have to tell the Board that PCORI has a broad and complex mandate and within that mandate one of the priorities is to address disparities.

As I said, it is one of our five national priorities for research. The legislation specifically calls it out. And the reason that I’m bringing this up is because sometimes I do get asked, why a focus on addressing disparities, and I think it’s important to note that a focus on reducing disparities, particularly through comparative effectiveness studies that focus on populations that have, for a very, very long time, been at risk for experiencing disparities can actually provide us with lessons from multiple groups.

We know that vulnerabilities are not uni-dimensional, they’re not mutually exclusive. I
know that all of you keep up to date with the news. We keep hearing about increasing income inequality and we know that low SES is a driver of disparities as well. So, the studies that we are funding at PCORI through the program, I think, have implications across a broad population.

Also, just from a foundational standpoint, persistent disparities in healthcare, which, you know, many of the people on the Board have contributed to the vast literature that has identified the existence of disparities, but persistent disparities in health and healthcare really does violate a widely held societal norm within the United States around equality of opportunity and the dignity or each person to be able to live their life at the highest level of productivity.

So, it’s an important focus for PCORI, it’s clearly a very important focus of the program.

So, I want to anchor the Board and those listening to our program’s mission statement, which
really aligns with PCORI’s vision, which is for patients and the public to have the information that they can use to make informed healthcare decisions about healthcare outcomes that are important to them.

So, PCORI’s mission is to reduce disparities in healthcare outcomes and to advance equity in health and healthcare, and I think it’s important to recognize that intersection between health and healthcare. We all know that health outcomes are not determined solely by what happens within the four walls of the clinic or a hospital. Community context, neighborhood context is incredibly important, where people eat, play, pray, go to school, et cetera, is an incredibly important context in terms of improving healthcare outcomes and improving health overall.

So, as I talk about some of our specific projects, you’ll see some of that intersection highlighted.

Our program’s guiding principle is to
support comparative effectiveness research that will identify the best options for eliminating disparities. And I have been asked and have been questioned about having such a lofty goal, and I would say that goals should, in fact, be lofty and I don’t think that this is a lofty goal. We have had some evidence of actual elimination of disparities despite the fact that they remain quite pervasive.

So, for example, David Williams, who’s at the Harvard School of Public Health, has pointed out that phenomena and flu, which is the seventh leading cause of death with about 65,000 deaths per year, the disparities between blacks and whites in 1950 were huge, 70 percent mortality for blacks compared to whites. That disparity has pretty much been eliminated. So, I do think that we should have goals that are REACH goals, but have realistic measures of success that are more proximal along the way.

I also want to emphasize that one guiding
principle of the program, which is really not stated here, is that we want to also fund comparative effectiveness research with a focus on patient-centered outcomes to actively eliminate disparities, not just describe the problem. We’ve had just, you know, a very, very rich evidence base that has described the problem for many, many years. In the last ten years we’ve begun to understand some of the drivers of disparities. We recognize that they’re multidimensional. There’s not just one driver, there are many, many drivers. So, the interventions that we fund and that we support through the program tend to be multidimensional.

On this slide you can see kind of the high level programmatic goals to identify high priority research questions relevant to reducing and eliminating disparities and healthcare outcomes to fund comparative effectiveness research with the highest potential to reduce and eliminate disparities and then to disseminate and facilitate
the option of promising practices, which hopefully
can become best practices, but again, realistic
measures to reduce and eliminate healthcare
disparities.

So, this just gives you, again, a pretty
high level overview of where we are to date in
terms of what we have funded. So, through our
broad PCORI funding announcements, which are our
investigator-initiated projects, through the four
cycles that we have funded to date, and at the end
of this week we will be reviewing our fifth cycle,
so we’ll have more projects in the portfolio, but
we have funded a total of 31 comparative
effectiveness research projects totaling almost $53
million.

The Addressing Disparities Program is also
the first program to release a targeted funding
announcement focusing on uncontrolled -- treatment
options for uncontrolled asthma in African-American
and Hispanic/Latino populations. We have funded
eight comparative effectiveness research projects
totaling over $23 million. So, to date, the
investment that PCORI has made in projects that
very specifically target disparities and
disparities populations is $76 million.

What we have in the pipeline, you can see
the three bullets here, are projects at different
stages. So, let me highlight the first one, which
is obesity treatment options in primary care. This
is focused on diverse populations. This was the
second targeted funding announcement that the
addressing disparities program released in February
of this year.

We will be reviewing applications in
August and we’ll be making awards. This year we
expect to fund up to two pragmatic trials with an
investment of up to $20 million in this area. I
should tell you that we instituted a competitive
LOI for this process. We received 48 LOIs and we
invited 11 --

[Audio drops for three minutes.]

MS. HASNAIN-WYNIA: A substantial part of
our portfolio also focuses on mental health projects. I should say that 19 percent in the Addressing Disparities Program, but if you look across all of PCORI’s portfolio, about 32 percent or 33 percent -- we’re still really looking through this information -- focuses on mental health. So, it’s a topic that cuts across all the funding priorities.

MR. BARNETT: Romana, is this by dollars or by numbers of projects?

MS. HASNAIN-WYNIA: These are by numbers of projects.

I also want to highlight the target populations. So, what you see here are the target populations for the disparities program, but what I’ve provided for you here is a chart that shows you, again, by number of projects, the target populations. So, the blue bar gives you the number of disparities projects that target specific populations. These are not mutually exclusive, so individuals can be from rural areas and low-income,
for example, but we also give you the numbers for
the entire portfolio for the four cycles so far.

So, the denominator here is 190 projects.

What you can see is that for a third of the
projects, or a third of the projects that focus on
racial and ethnic disparities come out in the
Addressing Disparities Program. It’s a total of
109 projects total across all the programs, but the
important point that I want to highlight here is
that the Addressing Disparities Program targets
projects with a focus on reducing disparities.
That’s the intent of the interventions and the
studies that we’re funding within the program.

For the other programs, it may be that for
some of the populations, it is a target, but for
others there may be subpopulation analysis, but we
don’t know if the studies are actually powered to
actually make definitive conclusions.

So, just to kind of highlight the balance
here in terms of what the target of the disparities
program is, which is to target a disparity, and we
expect the applications that come to us to really motivate the rationale for the proposal in terms of the impact of the condition, the burden of the condition, and so forth, and particularly for the specific populations that you see highlighted here.

DR. DOUMA: Could I ask a question on that? Quick clarification. I just head you say, correct me if I’m wrong, that we have 109 research projects in the AD arena?

MS. HASNAIN-WYNIA: No. We have a total of 39 projects in the AD arena.

DR. DOUMA: Thirty-nine.

MS. HASNAIN-WYNIA: What you see here are, if you look at the X-axis, it gives the target populations. So, the target populations for the program are racial ethnic minorities, low-income populations, rural populations, individuals with no literacy or numeracy, individuals with disabilities, and LGBT.

DR. DOUMA: Right, and these numbers have added up higher because of the overlap you already
MS. HASNAIN-WYNIA: Exactly

DR. DOUMA: Are there any other disparities groups that are not there?

MS. HASNAIN-WYNIA: So PCORI has a much longer list of what we call priority populations. So, within the priority populations, so for example, the elderly are included in PCORI’s priority populations, so they’re a priority for PCORI, and clearly we have projects within the Addressing Disparities Program which address the elderly population, but often with a cross-section to another -- to a target population for the Disparities Program, so, racial and ethnic minorities who are elderly, for example.

So, this is the target population for the program itself.

DR. DOUMA: But you’re saying some programs or projects here, there’s already -- there are some of the ones that are low income who are also racial and ethnic?
MS. HASNAIN-WYNIA: That's right.

DR. DOUMA: So then why wouldn't elderly show up, which are also racial and ethnic?

MS. HASNAIN-WYNIA: They would, but we're not categorizing them in terms of the bar graph here. So, they're embedded in here, but we're not highlighting them within the bar graph.

DR. DOUMA: Okay.

MR. KUNTZ: Just a quick clarification. I'm still a little bit confused about the PCORI projects addressing disparities. If you culled them out of the overall PCORI projects about addressing disparities but then said that they weren't necessarily powered to define those --

MS. HASNAIN-WYNIA: Yes, so the title should probably be changed and I apologize for that. So, these are -- so, what we have here is -- so, initially what I had was just the Addressing Disparities portfolio, which showed the 31 projects that focus on racial and ethnic minorities, the 25 that focus within the program on low-income, and so
forth, and then we also were -- are very interested in seeing whether there are cross-cutting projects to cross all the programs.

So, one of the things that we started to look at was what other programs within PCORI address target populations that are at risk for disparities. So, the projects in the red -- so, 78, 59, 53, so on and so forth, are projects in the other programs where the investigators have identified these as either target populations or in their sub-population analysis, but we don’t know at this point because we haven’t had time to really dig deeply into all of the other projects in the different portfolios to see whether all of these projects are powered sufficiently for the sub group analysis.

So, I can’t speak to that --

MR. KUNTZ: I'm just being a little nitpicky. I think that if somebody has an objective to address something that has to be powered, we can’t just say that --
MS. HASNAIN-WYNIA: Right, I mean, I think you raise an important point. So, the title for this should be basically a focus on which projects include underserved populations, not necessarily that they’re addressing disparities.

MR. KUNTZ: And then the question is different. The question is, within the group, what works, which is actually very valid. You’re not making your contrast and you’re not contrasting those individuals with the control group, which would be non-disparity people, right?

MS. HASNAIN-WYNIA: Right.

So, we also wanted to highlight the research methodology. So, again, 39 projects within the disparities program total that we have funded to date. So, of those 39 projects, 33 of them incorporate a randomized control trial. Many of them are mixed methods, which have a randomized control trial component.

There are a small number of studies that are not randomized control trials, they’re quasi-
experimental or observational. They are
comparative. They have comparative components.
One of the things to highlight here, however, is
that, again, reflecting back on the disparities
populations, for many of the populations, for low
SES, for racial and ethnic groups, we have a great
deal of evidence about disparities. For some of
the other populations, we just don’t have that much
evidence, so individuals with disabilities, the
LGBT population, so some of the work that’s coming
forward that targets these groups are not
necessarily randomized control trials, they’re
quasi-experimental or they’re observational,
they’re providing an important contribution and
laying an important foundation, but they’re frankly
not ready to move straight into a randomized
control trial at this point.

Again, they’re a very small number.
Eighty-five percent of the portfolio focuses on
randomized control trials. Yes?

DR. WEISMAN: The thing about what you’re
saying and also the fact that -- this is Harlan Weisman -- of the other studies that may not specifically be looking at disparities but have these populations included, do we have any kind of standardization on the kinds of data that’s being collected that go to this? You know, we bemoan often that other studies that have happened, whether they’re registries or randomized trials, use different definitions, different lexicon, and therefore it’s hard to aggregate or look at things and the same question in different places, but among our own studies, there might -- you know, it seems to me there would be virtue in ensuring across certain variables that we’re defining things a certain way. Do we do that?

MS. HASNAIYN-WYNIA: Yes. We do to a certain extent. So, in terms of looking across the entire portfolio, are we looking at how we define rural populations?

DR. WEISMAN: Well, I meant more or less replicating findings in one study, whether you
would see it if you looked at -- it may not have been the primary intent of another study, yet those people were there and those variables were there so you could look at --

MS. HASNAIN-WYNIA: Yeah, so that’s -- so, in terms of looking across the entire portfolio, yes, and part of what we’re actively working on right now is a lot of cross collaboration across the programs as we’re each really digging deeply into our portfolios to see what we have individually and also where there’s overlap, and I think, you know, that really does present the opportunity to do exactly what you’re suggesting.

DR. ZWOLAK: This is very nice, 39 studies --

CHAIRMAN NORQUIST: Bob, can you say who you are?

DR. ZWOLAK: Bob Zwolak, Board. Sorry. Thirty-nine studies, $76 million, are they meeting milestones? And when are the results going to start rolling in?
MS. HASNAIN-WYNIA: Yes --

CHAIRMAN NORQUIST: Why don’t we -- so, let’s let her finish. If we have clarification questions, I suspect that’s going to be coming up, is that correct?

MS. HASNAIN-WYNIA: Yes.

CHAIRMAN NORQUIST: So, why don’t you go ahead and if we have clarification questions --

MS. HASNAIN-WYNIA: Okay. So, I want to highlight a couple of studies and I can go ahead and actually answer the question about milestones, yes, we’ve begun to get our first set of milestones from the first set of projects that we have funded and they are all meeting their milestones so far.

Many of them are underway and we’re expecting reports in the next couple of months, but for the reports that we have been getting, all of the projects, actually, within the Addressing Disparities Program, have been meeting their milestones.

I should also say in terms of assessing
milestones, we have been working very closely with the engagement team. As many of you know, engagement officers have been working with the science staff in terms of really not just monitoring the scientific milestones, but also the engagement milestones for each of the projects and those are integrated throughout all of the milestones for all of the projects.

So, we really hope to have some very robust information about not just the scientific milestones that are being achieved, but also really, you know, very robust information around the engagement milestones as well.

So, there are a couple of projects -- again, you know, there are 39, so I’m just going to be highlighting a couple of these to give you a flavor. We’re really excited about this project, which is led by Ken Wells at UCLA. It’s a project that looks at long-term outcomes of community engagement to address depression outcome disparities. This takes place in South Los
Angeles, which there’s basically a population of about two million people, which is six times the size of New Orleans.

It’s important to note that there is no public hospital, there are very, very few primary care practices, so this is a project that has really focused on engagement of the community and really building off the assets that the community currently has.

So, it’s a mixed method study. The long-term outcomes focus on three-year outcomes, again, focusing on depression. There is a randomized control trial component, so 95 service providers are being randomized to either a technical assistance arm where the clinicians are being trained, the sites are being trained around medication management, webinars around cognitive behavioral therapy for depression, et cetera, and then the active intervention arm is also providing technical assistance, but with a very strong community engagement component, so really helping
these providers and these organizations network
with each other and network with community-based
organizations.

This has really been a great model in
terms of PCORI’s vision around engagement. The
community engagement component collaborating with a
large academic medical center has really played out
on kind of equal footing. Loretta Jones is the CEO
of Health African-Americans and sits as a co-
investigator. They present together at national
conferences. There’s just a very positive view of
this project within the community as well and
really does offer very strong lessons in terms of
the importance of engagement and collaboration.

The other piece that I think I really
would like to highlight here is that there is a
clear focus here on both a healthcare system
intervention working within the context of the
community, so again, there’s more information about
this project than I can obviously share with you,
but I wanted to highlight this partially because
the methods follow many of the -- the model follows many of the projects within our portfolio which are mix-methods, again with a -- sometimes a strong qualitative component or a quasi-experimental design coupled with a randomized control trial.

So, the second project I’d really like to highlight, because this does focus on one of our high-priority areas, which is reducing health disparities in Appalachians with multiple cardiovascular disease risk factors, again, this project takes place in Kentucky, the study is based at the University of Kentucky, very, very high risk disparities population in the 1 percent for cardiovascular risk, very low-income.

This study focuses on a randomized control trial. Again, very strong engagement, patient engagement and stakeholder engagement, it compares two approaches to reducing cardiovascular disease risks among at-risk individuals in Appalachian Kentucky.

The goal is really to develop a model and
a tool of engagement so people can be very self-directed and have the tools to be able to address some of the CVD risk factors that they experience in this community.

This project is, I think, a fascinating project because it focuses on the Frontier county. It’s based at University of Montana. There’s very little data available on Frontier counties. So, Frontier counties are focused on areas that are pretty under-resourced because of the wide kind of geographic spread, very, very low population density, we’re talking about maybe six people per square mile, so clearly there’s a real challenge in terms of the services that are offered.

So, this is a non-randomized control trial. They use a quasi-experimental, mix-methods design to compare this model that they’re developing called the Roadmap against standard practice to improve outcomes post-discharge for people with chronic conditions.

And then the last project for now that I’d
like to highlight is this project that focuses on improving the quality of care for individuals with disabilities. This focuses on Medicare beneficiaries with disabilities within the primary care setting. Again, very little data available in this area, so this study is based at the University of Pennsylvania under Margaret Stineman’s leadership. Again, very strong patient engagement and we really think that this will provide an important tool setting the groundwork for maybe a future randomized control trial, but it focuses on both provider education, primary care clinicians, as well as patient education to advance quality of care in the primary care setting for individuals with disabilities.

So, I’m being very mindful of time so I’d like to move quickly, if you don’t mind, into kind of a larger snapshot of our project and where we are to date.

So, one of the things that we started to really think about in the program was to ensure
that we had some kind of a conceptual grounding for the work that we’re funding and to be able to map that to a conceptual framework that’s been vetted and accepted.

We looked through a number of different models, there are many out there. Amy Kilburn [phonetic] has a great model that focuses on improving health outcomes and reducing disparities within the context of the healthcare system. We have adopted Lisa Cooper’s model, which was published in JGIM, the Journal of General Internal Medicine in 2002. Part of the reason that we’ve adopted this model as a conceptual framework for guiding our work is because the inputs are multi-dimensional, as you can see, but the outcomes are very patient-centered in terms of morbidity, well-being, functioning, the patient’s experience of care.

So, again, this is kind of the underpinning or the guidepost for the program.

What we’ve done is we’ve taken this and
then we’ve put an overlay of what we call a driver model. This is very program specific. This doesn’t fit within the larger world. It really is just program specific within the context of the Disparities Program.

I know that many of you who use driver models are used to seeing them going from the right to the left. This goes from the left to the right partially so it maps to the conceptual model, also because of how we’re defining these drivers. So, I just want to very quickly -- you should have this in your Board book, but I just want to quickly describe what we mean by drivers.

So, we know that disparities are multidimensional. We’re all aware of this, and so we’re looking at what we consider the primary drivers, which are the higher level factors that may influence our main outcome here, which is to reduce and eliminate disparities, so policy level factors, organizational point of care.

The secondary drivers are elements or
concepts that can influence policy, that can influence the organizations or the healthcare system, or what happens at the point of care. And then within the context of the tertiary drivers, these are actually the interventions that are embedded within the projects that we’re funding. So, we’re going from very granular to a higher level.

I didn’t draw arrows here because the arrows can go in multiple directions, so if you’ll just bear with me, I’ll show you how we’re beginning to use this.

So, this is an evolving tool. It’s something that is dynamic, that will change, we’d appreciate your input, but part of what we’re doing is trying to map all the projects that we have funded to get a sense of what we currently have in our portfolio.

So, we have, you know, a broad array of projects, as you know, that address a wide variety of conditions, that address different patient
populations across a number of settings. So, I’m going to use one of our asthma projects to kind of highlight how we’re using the driver model.

So, this is a project that was funded through our asthma-targeted funding announcement. It takes place in Seattle, has three different arms, it’s focused on guidelines to practice, reducing asthma health disparities through guideline implementation. The three arms, you can see, focus on a health plan intervention plus provider education. Another arm focuses on community health worker home visits and self-management support, and the third arm focuses on enhanced clinic care with decision support.

There’s a high level of partnership in this project. Allina Healthcare, which is a Medicaid health plan, is engaged. The Seattle and King County Public Health Departments health system, so we have a lot of cross collaboration, very strong patient engagement as well.

So, one of the interventions focuses --
one arm focuses on community health workers. So, we’re interested in where use of community health workers may have an impact on secondary drivers such as enhancing or expanding the workforce or working within the context of the community or the home environment.

Another aspect of this study focuses on team-based care and self-management, so again, we can map these to the secondary drivers.

What I can say is that, as far as the outcomes that are measured within this project, which are incredibly focused on clinical outcomes and patient experience of care, functionality, provider-patient communication, are all point of care interventions with a component of organizational or system-level focus as well. But if you look at all of our programs in terms of all of our projects, what we have funded to date, the red flags basically show you the number of projects and what drivers they align to. And you can see here that -- I’ll highlight -- the top three
drivers that we have funded so far within the program focus on self-management, working with community health workers, and the tailoring of tools and resources around culture and language.

In terms of the secondary drivers, what the program has funded to date focuses on access to care, high quality care, training and education, and patient empowerment.

Most of the projects that we have funded really, in terms of the primary driver, focus on point of care or communication interventions. A small number focus on organizational level interventions. We do not have any projects that primarily focus on policy level comparing different policy level interventions.

Again, I want to emphasize that this is program-specific, so when we’re looking at primary drivers, we’re really looking to see, are there outcomes within the projects that we’re funding that may focus on policy-level comparators? We don’t have those within our portfolio, and in some
ways that makes sense given PCORI’s mandate, but
this might also tell us where we may need to
collaborate with other funders, with others who may
be focusing on policy level interventions to maybe
focus on patient-centered outcomes.

It also tells us where we’ve already made
a great deal of investment in a given area. So,
again, we’re really trying to take a great deal of
data, reduce it to a level that we can understand
where our investment is going so far, and where we
may want to make an investment in the future.

We know that even with point of care
interventions, we would hope that it would affect
policy, that it would affect what happens at the
system or at the organizational level, but again,
the focus here is on what the program has currently
funded to date.

So, I should have brought this up earlier,
but this is basically, again, these are the number
of projects that include underserved populations in
PCORI’s portfolio. And, again, all the projects
within the Disparities Program clearly focus on underserved populations.

We’re beginning to really move forward with developing learning communities among PCORI-funded projects, so we hope to start to host learning communities this fall. We’re excited about working with the engagement team under Jean’s leadership to really develop mechanisms to foster cross learning among project teams, but also, even more important, to really bring together the research community in a given area, so we’re going to start off with asthma with end users, so bringing together patients and payers and employers to really interact with the research community to inform what it is that they’re looking for as well as to allow some facilitation of dissemination early on versus waiting for the projects to be completed before we actually move forward with dissemination activity. So, we’d like that to happen a little bit more organically at the beginning of our cycles rather than after the fact.
So, we’ll continue to hopefully develop a more sophisticated understanding. We would really appreciate your input in terms of how we monitor our program and how we can also go about disseminating the best and promising practices and partnerships with our key stakeholders.

CHAIRMAN NORQUIST: Okay, so let’s -- we’ll go around the room. We’ll start -- Larry had his card up first there. We’ll just go around this way.

MR. BECKER: This is wonderful.

CHAIRMAN NORQUIST: Larry, your name.

MR. BECKER: It's Larry Becker. Sorry. I think this is wonderful and I think that it’s beginning to show sort of how we’re bringing everything together. And I think we know that if patients are intrinsically motivated, that’s the best way to get them to change.

So, here’s sort of a rhetorical question and how do we know that the things that you have up here are driven by what patients really want? And
I ask that question to say, as we begin to communicate this stuff, if we could show the linkage, all the hours and months of work we’ve done to link those two things together, I think this is amazingly powerful.

MS. HASNAIN-WYNIA: Yeah, and we can definitely do that. I mean, that’s part of why I brought up the fact that we’re really actively monitoring the milestones, not just on the scientific side, but on the engagement side. So, I think that we can really start to develop a very comprehensive framework in collaboration with the engagement team.

So, part of our goal is not just to look at whether the outcomes are improving on the clinical side or the systems level, but is this really driven by what patients want, what family members want, what caregivers want. So, that is part of our, you know, kind of active, strategic portfolio management to get a comprehensive picture of that.
So, what I provided here was, again, just a snapshot.

CHAIRMAN NORQUIST: Okay. Rick, I think I see your card there.

MR. KUNTZ: First of all, congratulations for really putting together a fantastic --

CHAIRMAN NORQUIST: Your name, please?

MR. KUNTZ: Sorry. Rick Kuntz, Board member. Congratulations on putting together a really nice portfolio and I think that this is a really important part of the PCORI. My question is, while there’s a methodology process to review these grants, one of the grants you showed was quite complicated with the matrix, three arms, I wasn’t quite sure what the control arm was. Could we have the Methodology Committee review a few of these just to make sure? Because CER is probably the most complicated of the methods we’re going to develop. I, frankly, couldn’t find how you were going to be able to tell what the winner was, in that one study, but none of us had a chance to
really review that.

But I think that the Methodology Committee could really help calibrate grants as we go along to look at certain examples of this and potentially provide a report back to the Board with respect to whether or not the methods that they espoused are actually being incorporated into the [inaudible].

MS. HASNAIN-WYNIA: I think that's a great idea. And I’m sorry, yes, the comparator arm was the health plan intervention. Everybody is getting that. So, I should have identified that.

CHAIRMAN NORQUIST: Okay and now Sharon Levine, who’s a Board member, will be speaking. I’ve decided this is the way to do it instead of --

DR. LEVINE: No trust, no trust. Sharon Levine, Board member. So, looking at disparities in health outcomes versus healthcare outcomes, the latter has an awful lot to do with the design elements in the delivery system, and it’s not clear to me from what you put up there. I looked at that page full of -- the one right before the drivers
and there’s nothing in there about design elements
of the delivery system or the site of care where
patients actually get their care, and I’m wondering
how you’re accounting for that and looking --
because part of our portfolio is health system
improvement.

MS. HASNAIN-WYNIA: Right. So, part of
what we have put into the broad funding
announcement, and that’s a great point, and a lot
of the work that I did before I came to PCORI was
I’m looking at point of care and site of care and
whether that’s a driver of disparities and how and
so forth.

So, part of what we’ve done is really
start to focus, partially also by -- through advice
from our advisory panel, is to embed within our
funding announcements that we are interested in the
studies that focus on disparities taking place in
settings where these populations get their care, so
within the context of community health centers,
public hospitals, more under-resourced providers,
so we can embed kind of the evaluation component of the design within that. 

So, many of our studies focus on that. Not all of them. So, hopefully we have the ability to do some comparisons at the design systems level, but many of them do take place within the context of safety net settings.

DR. LEVINE: So, I would argue that with – in a post-ACA world, it is going to be much more important to compare traditional care delivery settings with safety net providers because more patients in Medicaid and more low income patients are going to be accessing the traditional sites of care delivery and the ability to understand what that means is going to be increasingly important.

MS. HASNAIN-WYNIA: I agree. Thank you.

CHAIRMAN NORQUIST: Harlan Weisman.

DR. WEISMAN: Harlan Weisman, Board member. You know, I really liked what you were presenting and the kinds of questions that are being asked and probably what made me think about
it more -- these might be naïve questions -- but I was wondering, at the end of all this, what does success look like? Is it that disparities go away or the disparities get less? And how do we actually measure that? And from population to population, because we’re not looking at that -- let me just give you -- and then the question was how general -- you talked about changing practice -- this has the potential of changing practice -- to one of the things you presented, and I was wondering, practice where? You know, how generalizable is the findings from one study to -- across the nation or across different populations? And I’m just curious about what you were thinking about in terms of generalized ability, you know, whether it’s in systems geography or whatever. I’ll stop there.

MS. HASNAIN-WYNIA: So, I think these are great questions. So, in terms of measures of success, I think that part of the reason that I wanted to focus on having kind of a very lofty goal
of eliminating disparities, we realize that is
maybe a generation or two away, but we really do
think that we can move the needle in terms of
reducing disparities within specific areas.

So, part of this is going to really be
derived also through how we strategically focus on
our Targeted Funding Announcements and what we
focus on. So, as Joe said earlier, ensuring that,
you know, we’re bringing the right stakeholders to
the table very early on so the adoption -- the
dissemination, implementation, adoption of these
practices can start to happen early. So, I think
that is going to be one measure of our success is a
level of uptake, even if we are only seeing small
progress in terms of actually reducing disparities.
And it’s going to depend on the conditions that
we’re targeting as well. So, we have to be mindful
that a one-size-fits-all approach is not going to
lead to a reduction.

So, I think it’s really important for us
to keep that in mind as we start to measure the
impact of our program, especially as we approach 2019, because that’s a pretty short timeframe to focus on closing the gap as well as improving outcomes for everyone.

Your second question, in terms of the generalizability, I think that’s -- you know, many studies face challenges around generalizability, but one thing that I think, in a very simplistic way, is that if we can show that something works in a really resource-constraint environment, we would hope that some of these practices can be adopted in broader environments as well, because if it works in very under-resourced -- and that was part of our focus strategically around paying attention to safety net providers and under-resourced providers, so we’re hoping that we can have an impact on generalizability through that pathway.

CHAIRMAN NORQUIST: Thanks. I have to make an announcement here. Unfortunately, there were some technical issues, so for people who are listening, you can’t see the slides, you have to
log back in in order to see the slides. You have
to go to pcori.org/event and log back in so you can
see the slides.

Okay, Ellen, you snuck in there. Ellen
Siegel is now speaking.

MS. SIGAL: Sorry. Ellen Siegel, thank
you. It’s very important work. The issue, really,
will be in terms of implementation, the economic
feasibility, so it’s what we learn is going to be
important, so the issue is when the study goes
away, the economic ability to implement this is
really -- without the resources, is an issue years
ago I worked on clinical trials in community
settings and we came up with some really
interesting models to get underserved populations
involved in these trials, but unfortunately, the
economic model didn’t work, it was too expensive.

So, speak a little bit to how this all
works. Obviously, this is important, but the
ability to have the resources to implement is going
to be important.
MS. HASNAIN-WYNIA: Yeah, so, I completely agree and, you know, part of -- you know, sometimes we act before we study, so I’m reflecting back on pay-for-performance programs that were -- that have been implemented over the last, you know, ten years or so and quite a bit has been written about, you know, whether the pay-for-performance programs may, in fact, exacerbate disparities. But we are functioning on a model of kind of value-based purchasing. We’re moving forward with value-based purchasing in terms of the ACA. I think that there is, you know, a real focus right now in terms of how organizations are delivering care and being accountable not just for what takes place within the context of the healthcare system, but also within the context of the community.

So, when we look at accountable care organizations, patient-centered medical homes, I think that there are going to be natural economic drivers, especially when we start to link some of the work around -- if we use hospitals -- around
community benefit and such to what providers get paid for, that there will be natural drivers that may, in fact, support the integration of some of the findings that we derive from the evidence base that we developed to actually improve those outcomes.

So, I think that there is an opportunity here with the roll out of the ACA with new payment models, with new delivery models, to really begin to integrate a focus on disparities reduction versus, you know, just paying for overall quantity of care.

And it’s much more complex than that, clearly, but it is one component that we have talked about quite a bit in terms of kind of a natural influx, in terms of a focus on, you know, what could be an economic driver to really focus on reducing variations and disparities and practice.

CHAIRMAN NORQUIST: Allen Douma.

DR. DOUMA: I’m Allen Douma. Let me just say that this is one of the most important
presentations I’ve heard since I’ve been on the PCORI board. I think it’s taking us a dramatic step forward in understanding what we’re doing and after we understand what we’re doing, we have a much better idea of how we can do it better.

I would love to see the approach you take in your conceptual framework be applied to every study that we’ve funded and to use that as a guide to what we -- what is, where are the gaps, so we can fund better in the future, and hopefully they’re learning from your excellent work in how to apply it to everything else, including a searchable database across all the parameters you talked about.

Within the conceptual framework I’m particularly pleased to see the emphasis on things like self-management, a little bit of over-emphasis, in my mind, on self-management within a clinical setting, because so much -- most of self-care, for example, goes on outside of clinical settings, but you’re in that direction, in that
ballpark, and I love it. Compared to the rest of our research, I think we’re too far away from it.

The only thing that I would like to bring up, for a lot of good reasons, including I’m an emissary from AARP, is I would love to see more of a reporting and emphasis on the elderly.

And I do have one question. How do you prioritize, in your own mind, and how does that prioritization influence our decision-making with regard to which disparities or which groups that we want to focus on in the future?

MS. HASNAI-WYNIA: So, in terms of prioritizing, we have used the process that many of the other programs have been using, so we rely on the IOM-100. We started to do that early on even before the formation of the advisory panels.

Our advisory panel clearly provides us with some guidance in terms of topics and target populations. We do this through a pretty diligent process of looking at where, you know, a number of stakeholders have come together, such as the IOM-
100, some of AHRQ's future research needs, what's being funded at the NIH, we spend a lot of time talking to our colleagues at NIH, at AHRQ, and at CDC to really understand where some of the gaps are where PCORI can make a contribution.

And through that mechanism we then go through our advisory panels, prioritize, and then come forward to the Board and the respective committees to hopefully motivate and really hone in on a target topic as well as target populations.

CHAIRMAN NORQUIST: Okay. Debra and then Gail and then we need to wrap up because we're behind.

MS. BARKSDALE: Debra Barksdale, Board. Could you go back to slide 67, please?

MS. HASNAIN-WYNIA: Sixty-seven?

MS. BARKSDALE: Sixty-seven. Yes.

CHAIRMAN NORQUIST: You passed it. You're going the wrong way.

MS. HASNAIN-WYNIA: Sorry.

MS. BARKSDALE: That's it. Given that
there is a significant amount of work on disparities going on throughout PCORI, how do we leverage all of the potential knowledge that might be gained?

MS. HASNAIN-WYNIA: So, part of the leveraging is -- you know, part of this is a call from Bryan Luce, who’s our chief science officer, as you all know, is to really start working across the programs and looking at specific clusters of projects in a given area, and look at the focal points in terms of our national priorities. So, you know, which projects really focus on addressing disparities across the portfolio? Which projects, within the Addressing Disparities Portfolio, have a strong emphasis on improving health systems or on clinical CER? Which projects within the communication and dissemination portfolio cross over with the disparities portfolio? So, that’s the work that we have really actively just started and we really hope to be able to bring you a more comprehensive picture of that at a future board
meeting, but it’s something that we’re very mindful of. We recognize that, you know, our success is not going to be measured just by what happens within different programs, but across PCORI in its totality.

So, we’ve really been working as a team to really begin to understand that and develop those crosswalks.

CHAIRMAN NORQUIST: Okay. And that was Debra Barksdale asking the question. Okay, Gail Hunt will now speak.

MS. HUNT: Gail Hunt, Board member. I notice that in one of the three studies that you gave us as an example, I know that family care giving was an important component. I would just suggest that particularly in this area of disparities, although not exclusively, that you are absolutely sure that the researchers include family caregivers, because they’re such an important component in being able to do the -- to actually roll something out.
MS. HASNAI-WYNIA: Absolutely agree with you 100 percent.

CHAIRMAN NORQUIST: Rick Kronick.

MR. KRONICK: Rick Kronick, Board member.

One question, Romana, for you, and then one for my fellow Board members.

For you, following up on Ellen’s comment and actually also Allen’s, it does seem that for some of the tertiary drivers particularly self-management, the economic case may not be very hard to make and if you can show how self-management works, a lot of people will jump on that.

Community health workers, totally opposite, and I imagine that we ask when applicants are applying, but just -- the question, do we ask them, you know, what is the sustainability model? And, you know, how do you -- you know, if we show this works, how do you get from here to there?

Before you answer, then I will ask my fellow Board members, you know, this was an extremely useful presentation. It responded, I
think, at least in some part, to the question that Harlan asked at the end of the retreat, which was, were we able if asked to say what was it that we were doing in PCORI, that we’re funding, that we’re really excited to see the answers and we’re really looking forward, and I would ask my fellow Board members, having seen this now, are we better positioned at the next cocktail party when somebody says, okay, what’s PCORI funding that you’re really excited to see the results of, are we better positioned to do that?

CHAIRMAN NORQUIST: So, we’ll ask you first, though, what is your answer?

MR. KRONICK: I would say for myself, a little bit, but not too much. I would probably talk about the Ken Wells study and say might be some pretty cool things coming out of there, but I feel like I don’t really know enough about it and I’m not sure how excited I am about it.

CHAIRMAN NORQUIST: Yeah. So, what would make it more helpful, I guess, at this point?
MR. KRONICK: Probably a little more information -- I know it’s tough because there’s not much time.

CHAIRMAN NORQUIST: Right. We clearly did not set aside enough time and I think you’re absolutely right. I have the same feeling. I know about Ken’s stuff because I know Ken personally and I know he just won an award for this, but I think it’s true, we don’t know the -- and my answer to you would be, I feel somewhat the same. And so, there is an opportunity to learn from this experience, I think. Harlan?

MR. KRUMHOLZ: I just want to thank you very much, and Rick, thanks for remembering. There were some sticky messages from the discussion in San Francisco.

I just want to go back to at least the proposal that I’ve been making before and if we don’t do it on grants, maybe we can do it on presentations, which is -- and I want to give credit to John Eisenberg for this idea because I
remember having heard it at AHRQ, which is, give me the newspaper headline that comes out when this paper is first published or give me the abstract in the New England Journal of Medicine or whatever paper, the Journal of Community Medicine, I don’t care, that’s going to come out when this paper is done. Let me judge -- give me the most optimistic view that you have of what people are going to report on this, give me the most optimistic view of what that front page of the paper looks like.

I’m not criticizing --

MS. HASNAIN-WYNIA: No, no. I understand.

MR. KRUMHOLZ: But I'm trying to get us to focus on the value of the information by thinking about the end product. If the outcome of research is keeping the end results in mind, I’m trying to bring that mentality to the PCORI Board, and when we’re -- every single project, I want to see what that paper looks like in the most optimistic of worlds and what the headline in the newspaper looks like and the press release looks like in the most
optimistic of worlds. And don’t worry that you’re making assumptions about everything going right and the findings being, you know, as best as they possibly can, because I want to know what that is. Now, ideally when we’re doing the evaluation of the grants, I would like to see a mock paper without -- or even with optimistic results, what they would expect to see, a press release, and then I want some estimate of the likelihood of getting those results, because any good investigator will tell you, here’s what I would hope to see and there’s -- you know, either at equipoise or they could be a little more enthusiastic, but I want to know how high risk it is. But that may before the committee. But for us, when we’re being presented -- I think Rick’s bringing up a really good point -- for us to be good ambassadors and for this Board meeting to be able to communicate broadly to the people listening and for the audiences here with us today, the technical parts, and even the conceptual
model is less important -- many of us are deeply interested in this, but for many people this is inside baseball, is give us the headline. What’s the headline? If this is successful these are the three headlines you’ll see in three to five years. And that, I think, will help get us to the value of information. Was that headline worth $23 million or $10 million or $500,000? And that’s where I think we in the public will be able to take it in. You happen to be up, but I’m saying this broadly because I think that we need to find better ways to communicate this. Maybe the engagement group can help think about this too, but we need to find better ways to communicate this so that it’s sticky and people leave there thinking, I heard three studies that, wow, I can’t wait for those to come out.

And I would have the same trouble you’re having right now. I’m impressed, but I don’t -- I couldn’t do a teach back with me in the hallway and I can’t repeat to you, you know, the three things.
I could say asthma, but I don’t know what it is. I can say something going on in Montana, in Kentucky, that Mozer’s [phonetic] doing a great study or Ken in LA, but I can’t go beyond that.

CHAIRMAN NORQUIST: Yeah, so we have some work to do to get the message right and I think there’s another piece of the message here, which is not only the headline -- so, if you were writing this for The Washington Post, since we’re in Washington, or if you’re writing for The New York Times and it would get their attention, get the editor’s attention, and when I have this published, what would you say, basically. That would also help me understand these instead of I think sometimes we get lost in the trees here and miss the big point.

The other thing, I think, that’s also missing in this is what’s unique about it for PCORI, because there are a lot of other places that are funding. I mean, Dr. Collins has a lot of this going on at NIH and Rick does too, and I mean, the
question is, what’s unique for us? Because we can all sit here and say, this is wonderful to do, but really, what particularly also is it about what we’re doing that’s unique? What’s unique about your portfolio, our portfolio that I think would also be very helpful as part of the message also? Okay?

Thank you very much. I know you’ve done a wonderful job --

[Applause.]

MS. HASNAIN-WYNIA: Thank you. And thank you for the comments and the questions. They’re actually incredibly helpful for us.

CHAIRMAN NORQUIST: Yes, and I appreciate -- it’s all done in a collegial manner. We hope everybody understands that, right, we’re all trying to move forward in the same way.

And, Robin, we have taken out 15 minutes of your time. I don’t know if it’s going to still take you 30. We’ll have to try to make it up if you want to. You don’t have to, but I guess you’re
going to. Okay.

While Robin is moving up, make it real quick, Joe, because you’re going to use up some time.

DR. SELBY: Yep. I just have to say that for the record, Romana asked for an hour and I only gave her 45 minutes.

CHAIRMAN NORQUIST: Ah-ha. So, it’s your fault?

UNIDENTIFIED: She took the hour.

CHAIRMAN NORQUIST: She took the hour.

That’s right. The heck with Joe. She just took it. That’s your staff.

Okay, so next, Robin Newhouse, who is the chair of our Methodology Committee will be giving us an update on the Methodology Committee, correct?

MS. NEWHOUSE: All right. So, I’m going to try to do something innovative. Harlan’s inspired me. Methodology Standards Transform Science. PCORI Methods Task Force Identify Ways to Harmonize Data. Open Science Group Develops
Reproducible Research Standard. Decision Science: Improve Decisions for Clinicians, Patients, and Health Systems. And a little bit about an update with new Methodology Committee members. So, there you go, Harlan. We’ll give it a start there for your challenge.

Okay, so in terms of, first of all, the methodology standards, we are working on two sets of new standards that are important for PCORI. The first is around designs that use clusters and the second is around complex interventions. These are two areas where PCORI has invested in research studies, and they’re both important.

Complex interventions are those interventions that involve multiple components. They’re very difficult to disentangle. So, the idea that is we are approaching the development of these methodology standards in a little different way in that they are starting with a landscape review, moving toward working with experts that have already started work in this area, and will
result in workshops before standards are developed. So, we will be able to update you at the next public Board meeting about where we are with those standards. We expect that there will be a workshop in the fall related to the research designs using clusters. We don’t have a date identified for the complex intervention standards.

The second thing I’d like to update you on is many of us have received a number of inquiries related to new standards or recommendations for new standards. We’ve now developed a public forum for solicitation of ideas for standards. You see it -- this is just a snapshot of the PCORI website. So, now those that have a recommendation for new standards development can go right to the website.

Second of all, the Methodology Committee has identified a need to develop a task force related to identifying innovative methods that have evolved as gaps as PCORNet grows and is launched. So, that effort is led by Sebastian Schneeweiss and it is just getting started. The members of this
task force include Methodology Committee members, the PCORNNet coordinating center as well as PCORI staff.

The third agenda item, and Harlan, I might call on you. I know Steve is on the phone and if you have any additional comments to make, the open science workgroup has begun its work led by Harlan Krumholz and Steve Goodman, who is on the phone. This group is under the oversight of the Research Transformation Committee. And they’ve had one meeting so far and have developed at least a draft of direction. And, Harlan, do you want to say anything about that work?

CHAIRMAN NORQUIST: Could you say something, Harlan, about where we are at this point? Is Steve Goodman on the phone? I didn’t realize he was on the phone. Steve, are you there?

MR. GOODMAN: Yes.

CHAIRMAN NORQUIST: Okay, good.

MR. KRAMHOLZ: Steve, do you want to go ahead and start?
MR. GOODMAN: Sure. I’ll just say briefly, we developed a draft proposal that we discussed with the working group. Then Harlan and I have honed it down to a more concrete proposal that we’ll be representing to that same workgroup and we expect to have that to the RTC within the next few weeks or months.

MR. KRUMHOLZ: Yeah, and I just want to add to what Steve’s saying is that we’ve channeled forward a lot of the comments that we’ve heard over the course of the last several years, both from the Board and from external stakeholders and CS is being uniquely positioned to help push these forward both with regard to our actions and policies as well as our ability to create more normative behaviors. We’re, to be honest, riding the waves of a lot of other activity that’s going on in this area, but we want PCORI to be seen as progressive and as a catalyst for these kind of activities.

Steve is at an IOM meeting. Rick went
over this morning, I’m going to go over now. There’s kind of resonance back and forth with a lot of other efforts that are happening here and we appreciate the Board’s support and Methodology Committee’s support of the idea that PCORI can play a critical role in helping to push forward some of these very important areas of ethics within science.

MR. GOODMAN: Yes, I'll just add to that. While we are sort of riding the wave, one of the reasons there had to be such a wave is because most of the agencies and entities who could move this [unintelligible] forward, have constraints that maybe PCORI won’t have, and I think we can really be leaders in this space even though some of the technical challenges are actually somewhat daunting.

But I think there’s a potential for us to set the standard going forward. So, this is really quite an exciting area and you’ll hear from us in the near future.
DR. COLLINS: Francis Collins. I think this is great that there is a workgroup focused on this. Thank you, Harlan. Thank you, Steve.

Just remind us, though, what’s the process for bringing forward the output of your workgroup to the Board given that this is sort of an unusual group that’s partly connected with Methodology Committee and partly with the RTC. How is that all going to emerge?

MR. GOODMAN: Well, the current thought is the group itself will consider the proposal that we currently have on the table, perhaps modify it, and then that proposal will be brought into the RTC.

There are some elements of it that will absolutely require serious discussion and potentially commitment of resources or effort by PCORI, so this is the kind of thing that the recommending joint committee can’t decide by themselves but we can put the issues forward for the Board. And we expect to have that, as I said, probably in the next month or two at the very
MR. KRUMHOLZ: It would be ironic if a committee on transparency were to keep its intentions secret until the final moments. So, I think --

CHAIRMAN NORQUIST: I’m not worried about secrecy at all.

MR. KRUMHOLZ: So in seriousness, it’s our challenge to both make progress, do refinements, and then share at appropriate junctures where we can keep moving forward, but certainly this is going to be far too important for us to move forward at all without the full Board’s consent and enthusiastic endorsement as well as the Methodology Committee. I mean, I think if one group or the other is not completely 100 percent supportive of this, we’re going to have an issue.

So, we’re going to try to take steps forward, keep people in the loop, and then come back to the Board, maybe for the next meeting be able to present some of these ideas in a little...
more detail.

CHAIRMAN NORQUIST: But it sounds like the primary process -- I’m sorry, Steve, go ahead.

MR. GOODMAN: I was just going to say, this will be the subject of an hour-long discussion at the Methodology Committee meeting on Wednesday.

CHAIRMAN NORQUIST: Yeah, and this is Gray Norquist, but my sense is that this will come back through the RTC for the most discussion and then it will come to the full Board, correct?

MR. GOODMAN: Correct. That is the plan.

Yes.

CHAIRMAN NORQUIST: Thanks. Do you want to move on now?

MS. NEWHOUSE: Yes. Thank you. So, the last and additional exciting focus for the Methodology Committee in coordination with PCORI Board members and staff is the excitement around some of the decision science conversations that we’ve had.

The Methodology Committee workgroup has
worked on a framework for decision sciences and
they’re moving forward with several activities,
including a draft of a sort of framework and
they’re in the planning stages now of a workshop
again for the fall. They’re gathering more
information.

So, the framework just includes items such
as improving decision making for patients and for
health systems. Some of the others, decision
making when a patient isn’t able to participate in
meaningful -- participate meaningfully, how people
decide the factors other than evidence that affect
medical decisions, facilitating shared decision
making, so they’ve spent some time developing this
framework that can then be a basis for a workshop
to help advance some of our thinking about the
science, our decision sciences.

So, that’s a very quick update of some of
the activities that the Methodology Committee has
been involved in.

The last thing that we wanted to recognize
is that we’ve had four members of the Methodology Committee that have left, Sherine Gabriel, Sharon-Lise Normand, as well as John Ioannidis and Al Berg. Al Berg, we’re very sad that he is rotating off of the committee. He’s made major contributions from the beginning of developing the charter for the Methodology Committee when we were formed right to our current discussion about how we can work best as a Methodology Committee to serve the PCORI Board, and we will greatly miss him.

John rotated off a little earlier this year, but Al will be serving through June with us until we have replacements announced.

The Government Accountability Office did open a request for nominations for the Methodology Committee, which closed on April 11th, so we’re looking forward to embracing new members of the Methodology Committee to help us carry our work forward.

So, just to summarize, we’ve done quite a bit of work in terms of developing new standards,
particularly around areas that PCORI is investing in research. We have developed a taskforce, the PCORI Methods Taskforce, to identify gaps that are apparent through the PCORI network and Sebastian is leading that.

The open science work has begun to advance and you’ll hear more as that work evolves, as well as the decision science initiative that we’ve been heavily engaged in.

So, I’ll close with that summary and invite any questions that you may have about the Methodology Committee work to date.

CHAIRMAN NORQUIST: Thanks, Robin. These cards, I think, are from the last -- do I have anybody that has questions at this point? Or comments?

[No response.]

CHAIRMAN NORQUIST: Okay, thanks for that nice -- one thing I would ask, Robin, when do you expect kind of this -- we just heard about for the open science from the decision science. When do
you think you’re going to come to some conclusion, because that will inform kind of what we’re doing as far as what we’re funding and it might be nice to have that sooner rather than later.

MS. NEWHOUSE: We have our Methodology Committee meeting on Wednesday, so we will come to some conclusions about deliverables and dates so those dates have not been scheduled yet. So, we’ll get back to you after Wednesday.

CHAIRMAN NORQUIST: Yeah, so that will be important because we’ll need to let the field know about what our interests are, what they’re not, so that we don’t lead people into submitting applications in the future and stuff if it’s not something we’re going to think we’re going to fund or something, correct?

MS. NEWHOUSE: Yes.

CHAIRMAN NORQUIST: Okay. Harlan Weisman.

DR. WEISMAN: Harlan Weisman. Robin, in the past, there were concerns on the Methodology Committee, I think on the Board and maybe the
Institute about effective integration of the Methodology Committee in PCORI processes and utilization of the talents and capabilities of the Methodology Committee. And a number of actions were taken, I guess, over the last six months to a year. Can you give us a view of how you think -- how the Methodology Committee thinks things are going? Have there been improvements? Are the committee members feeling better about the integration?

MS. NEWHOUSE: I would say that the work and engagement of the Methodology Committee throughout the PCORI initiative has grown exponentially, not only as a result of many of the efforts that are undertaken by the PCORI Board and PCORI staff, but also in terms of the governance structure and embedding the Methodology Committee members in the different taskforce and in the groups -- the initiatives driven by the PCORI mission.

So, I think that we all are heavily
involved and I would say that I haven’t heard one
person say they would like to be more engaged. We
certainly have been actively engaged in anything
that PCORI has done.

CHAIRMAN NORQUIST: So, thanks for asking
that, Harlan. That’s an incredibly important point
and I’m glad to hear that that’s the movement we’ve
made, some success there.

Next, while we’re setting up here, Jean
Slutsky, who we’ve introduced earlier and we’re
very pleased to have join us, who was on the
Methodology Committee and at AHRQ, is now our chief
Engagement and Dissemination officer and Jean is
going to give us a brief update on Engagement
activities.

MS. SLUTSKY: So, Romana wanted an hour
and I wanted five minutes. So --

CHAIRMAN NORQUIST: And I made her take
15.

MS. SLUTSKY: We both got what we wanted,
okay. I can’t tell you how happy I am there’s no
cameras here so my evil double chin doesn’t show up.

Anyway, enough levity. First of all it’s, you know, an honor to be here. It’s great to be on this side of the curtain, so to speak. I’ve worked with many of you for a lot of years.

So, I became the chief Engagement and Dissemination officer on March 17th. On February 18th I became the program director for Communication and Dissemination Research. So, this is actually a nice diad. It allows PCORI to bring together two streams that are in the same organization but get much closer together. So, bringing communication, engagement, and science much, much closer together. And as many of you know how well things get identified as important topics and how we engage stakeholders throughout the research process has a great deal to do with how things get implemented in the end, and that’s something that obviously has been a lot of topic of discussion in this meeting and before this meeting.
and will continue to.

So, I don’t have a lot of new program direction to tell you. It’s a little early. I will say that I’m watching very closely this space with the Methodology Committee and their work in decision sciences because clearly, as we revise the PCORI funding announcement for communication and decision -- dissemination and communication research, we’ll be looking very closely at what the Methodology Committee comes up with.

So, I wanted to give you just some staffing updates. First of all, I have to say that the staff that I’ve worked with, both on the engagement side and the science side, although I will say the CDR portfolio that I lead is just me right now, but there’s been wonderful contributions from project officers from all the other national priority areas to pick up the slack, and it’s just been amazing to see how many of those people worked to develop projects that they’re not really responsible for.
So, the first engagement officer has been hired and we’ve made an offer, and I have to say now that offer has been accepted, for the director of the Eugene Washington PCORI Engagement Awards Program, and that individual starts May 19th. And I -- also new breaking news -- I made two offers for a senior and junior program officer for the CDR portfolio. So, hopefully they will accept and I’ll be an n of three for that portfolio, which, I think is exciting.

And we’re also developing under the engagement awards directions on how PCORI will fund large and small conference grants, which up until now has been somewhat ad hoc, and so this is really signaling to the field how -- what’s of interest to PCORI and how we’ll fund them.

And then kudos to the Engagement team. The edict, which put a great deal of effort into this, the patient and family engagement group has been completed and plans are underway to incorporate it into future funding announcements.
and to provide training to merit reviewers and
potential PCORI applicants.

And my last comment is that training is
now part of Engagement and we’re working very, very
diligently to provide continuing education and
continuing medical education training for many of
the training modules that have been given to merit
reviewers, the Methodology Committee standards, and
other activities we’ve done, not only as an
inducement for people to take part in these
activities, but to influence behavior in taking up
these training activities and standards.

So, you’ll be happy to know, or maybe not
so happy, that I have one slide -- well, two
actually with the title slide.

So, Gray, I can take some questions, but I
think I might have gotten you back on track.

CHAIRMAN NORQUIST: Oh, no, we’re going to
give you a lot of questions. Wait a minute. I
want to let Debra Barksdale say something if she
wants to since she’s chair of our Edict Committee,
which is the relevant Board strategy committee.

MS. BARKSDALE: Thank you. Debra Barksdale, Board. Well, first of all, I’d just like to give my appreciation to Jean and Orlando and others who -- I’m sorry if I missed someone, but those are the ones I’ve worked with most closely and I really appreciate the support that they have provided in helping us to develop the work of this committee and also to members of the committee as well that are around the table.

I think, as Jean has indicated, stay tuned, there is more to come.

CHAIRMAN NORQUIST: So, the other thing -- a couple things I wanted to say is, particularly on the last bullet, I think this is critical because we talk about how to train investigators in the methods and all this other stuff, but we also need to train them in what we mean by engagement. That’s really a critical issue and the more we can do on that to get that out is really critical, because every place I go now, particularly
academia, is like, what does this mean? What am I supposed to do? Can I just send a letter? No, you can’t send a letter. You know what I mean?

So, I think that’s really important and the more we can do on that.

The other thing that’s not in here because it’s not finished and it’s always a topic that comes up is, what are we going to do in implementation a la an interface with AHRQ? And that will come in September or some other time we’ll have that discussion, but we do have this contract out, correct, that we are looking at that’s supposed to inform us on that, but that’s where we are with that particular process now.

MS. SLUTSKY: Yeah, so, just a quick comment on that. The edict committee has been briefed and the Board was briefed, I believe, at the last committee meeting about the framework contract and AHRQ and PCORI have been meeting. The last time we met, I think, was a couple weeks ago, three weeks ago, perhaps, and we are setting up a
leadership committee between PCORI and AHRQ to meet once a month or bimonthly to set out a strategy for how we can coordinate our activities in this area.

CHAIRMAN NORQUIST: Okay, great. And then the other thing I would ask is, at some point we need kind of an update on what’s happening with the Eugene Washington Engagement Awards, I mean, as far as like where we are with those awards, kind of what’s in that portfolio also, I think.

MS. SLUTSKY: Yeah, so I’m really glad you brought that up because, you know, the person that -- in fact, this morning I spoke to the person who’s joining us as the director of the Eugene Washington Awards, so it’s a little premature to tell you about what we’re doing, but it is going to be a focus of trying to dissect if we’re sending a clear message to the field, how this fits in with the other engagement awards. And so, I guess, I hate to say stay tuned, but that’s definitely high priority on my agenda.

CHAIRMAN NORQUIST: Thanks. Freda.
DR. LEWIS-HALL: Freda Lewis-Hall. Jean,
I am sure you have answered this question for me
before, but the FDA is having kind of a fairly
large and expansive set of activities to engage
around drug development and safe and effective use,
and I’m wondering if we have any plans or have
initiated any interface with them or if you believe
that’s appropriate.

MS. SLUTSKY: We actually had a rather
large meeting with our FDA colleagues about two
weeks ago talking about how we can share best
practices. It actually was supposed to be an hour
meeting and Sue, you can correct me if I’m wrong,
but I think it lasted almost two and a half hours
where they were very interested in what we were
doing; we were very interested in what they were
doing, but they came away saying that they’d
learned a lot from our engagement activities at
PCORI.

CHAIRMAN NORQUIST: Others?

MS. SLUTSKY: Joe, you can’t ask any
questions.

CHAIRMAN NORQUIST: You can’t ask a question.

DR. SELBY: So, thank you, Mr. Chair. Joe Selby. Jean, you moved pretty quickly over the engagement officer and I’m not sure we’ve ever really discussed engagement officers with the Board and I thought you also mentioned the rubric and I thought a little bit more information on what these engagement officers are going to be doing and how the rubric might fit in would be good.

MS. SLUTSKY: I apologize. I didn’t know that the Board hadn’t necessarily been briefed on this.

The engagement officers, it’s a new concept where we pair individuals who work with the different portfolios and the investigators on developing and monitoring the engagement plans and ongoing funded projects. And, for example, we have an intern who’s working closely with the Patient-Powered Research Networks. Just hired someone
who’s working with other portfolios on their funded projects. So, it’s to really draw someone in to help monitor the engagement plans as well as how we’ll they’re doing.

The rubric is -- and Sue could probably give a much more detailed discussion of that, but it’s really a framework and discussion about how to develop an engagement plan, how to engage patients and families in developing your research study and monitoring your research study, and it allows people -- it shows people actually how to develop an engagement plan as part of their research application.

CHAIRMAN NORQUIST: Sharon.

DR. LEVINE: Yeah, that is a really terrific --

CHAIRMAN NORQUIST: Sharon Levine talking now.

DR. LEVINE: Sharon Levine, Board member. Sorry. One out of two isn’t bad. This is a really important piece of work because I think one of the
most confusing things about PCORI’s out of the gate request for proposals has been, well, what the heck do they mean by engagement, what are we supposed to do, how are we supposed to represent this, and our own concern about people putting words on paper and not actually knowing what to do with the words they’ve put on the paper. So, this is fabulous.

MS. SLUTSKY: Well, I can't take any responsibility for it, so kudos to the engagement team for pulling it together, but I’m happy to take your gratitude on their part.

CHAIRMAN NORQUIST: You know, I think we’re all very appreciative of that. You can take credit for keeping it moving forward. At least it didn’t come to a screeching halt when you came, right?

Okay, good. Thank you, Jean, very much. You’re off the hook this time. Just wait until next time.

And next, before our break, Michele Orza – where’s Michele? Oh, good. Okay. So, Michele,
who is the senior advisor to our executive
director, Dr. Selby, is going to present the
Evaluation Framework and Plan and we gave her 30
minutes. I expect we’ll have more discussion on
this one.

MS. ORZA: Thank you. So, it’s often said
that everyone thinks that evaluation is a good idea
but nobody likes to be evaluated. But at PCORI we
are different in all things and we are actually
extremely excited by the opportunity created for us
by our leadership to evaluate the heck out of
ourselves and welcome evaluation by others as well.

The work I’m going to discuss with you
today comes from a large and enthusiastic and truly
cross-cutting team of staff from every department,
the core of which is led by Laurie Frank in our
Research Integration and Evaluation Unit, and we
are extremely grateful for the assistance of our
evaluation task force, which is composed of three
Board members, Gail Hunt, Bob Jesse, and Bob
Zwolak; three Methodology Committee members, Robin
Newhouse, Mike Lauer, and Naomi Aronson and several external experts as well. So, I’m pleased to have the Board and MC members here with me today so that when my allergies cause me to lose my voice, you can chime in and fill in the rest of the story.

So, because we have committed at PCORI to functioning as a learning organization, when it comes to evaluation, the joint is really jumping, and I’m only going to be able to give you really just a flavor of all the things that are going on under the heading of evaluation.

I have some modest objectives for this presentation, to give you an introduction to some of the things we’re doing with evaluation, to give you a progress report on some of the core activities, and at the end, to give you a guide for how you can follow up and dive in and help us with making this progress further.

I'm pressing the wrong thing here.

So, currently we’re focused on three main sets of tasks, the first is to build our evaluation
framework, that is to delineate and prioritize and flesh out all the questions that we and our stakeholders have about patient-centered outcomes research in general and about PCORI specifically, determining how we can measure some of the key things that we need to measure, namely our goals -- our three goals that we established, and engagement in research, the discussion earlier about what exactly is engagement, what do we mean by that, how does one do it, and what effect is it having.

And then, finally, we have a lot of evaluation activities that have been underway and are being initiated on things that we already know are high priority such as surveying certain audiences and starting to attempt to assess the impact that engagement is having on our work.

So, what is an evaluation framework? It, very simply and straightforwardly, is the organization of all of our questions and the explanation of how we’re going to go about answering them.
So, at the end of the day, it’s a giant table that has these fields, the first column lays out what the question is, the second column lays out the metrics or the measures that you need in order to answer it, the third column describes the method by which you’re going to go about trying to answer the question, and the fourth column describes the sources of the data that you will need in order to answer that question. And at the end I’ll show you what this looks like for one specific question.

So, our evaluation framework is all encompassing, it’s everything that’s going on with the entire organization and so it’s very large and kind of overwhelming, but we break it down into three sets of questions. The first set is -- are the questions about our day-to-day work. So, what are we doing? How effectively are we doing it? Are we on track? And most of these questions wind up being reflected on our dashboard. I’m not going to say too much about this bucket because Joe is
going to go next and talk you through our dashboard except to say that there’s a lot of interesting stuff in here and even though we’re just at the stage of kind of describing what’s going on and counting things and laying things out, you really learn a lot in that process.

Fred Mosteller always used to say that the first three rules of data analysis were, look at your data, look at your data, look at your data, and in doing that we learn a lot, we gain a lot of insight, and we develop a whole lot more questions.

So, Joe will be going over -- I think there’s almost three dozen metrics on this one page, he’ll be going over that with you next.

The second set of questions are the questions about our three goals. Are we on track? And are we, in fact, accomplishing those goals? And what I’d like to tell you is just a little bit about how we’re going about tracking and measuring the attainment of each of our goals.

So, the first goal, as you all know, is to
produce useful information. So, every word in this statement of our goal is important. We are, for example, we have a whole set of methodology standards that go toward ensuring that the information that results from our studies is of the highest quality and is trustworthy, but what we’re really focused on in terms of developing metrics and in terms of defining success on this goal is producing useful information.

And so, we’ve been focusing a lot of attention on how do we define and how do we measure useful information.

We set about doing this by asking the users or the people who -- the would-be users of the information, what would make it useful for them. So, we looked at the literature on this. We partnered with the National Health Council on an effort that they had to define these criteria, and we’ve been consulting with our advisory panels and our patient engagement advisory panel and a variety of stakeholders to ask them what would make
information useful to you so that we can then translate those into criteria that we would try to bake into our processes so that the information that results at the end is useful.

This is a draft set of criteria and what we’re doing with these now is pilot testing them on some of our applications and cross-walking them with the criteria that we already do have, such as for topic selection or for merit review and the methodology standards to see to what extent we’ve already captured a lot of these things in our other criteria and to what extent do we actually have to develop new ones.

So, we can’t say anything much about the actual usefulness of our information until the studies are done, but what we can say now is to what extent does it look like these studies that we’re funding have the potential to yield useful information. And so the first thing we’re planning to do is, once we refine these criteria, actually apply them to our portfolio in the spirit of
saying, well, does it look like these at least have
the potential, if they are successfully completed,
to yield information that people will find useful.

And the other thing that we can do is we
can actually talk to our stakeholders about -- and
have them take a look at what’s in our portfolio
and let us know whether they think it has potential
to be useful to them when it’s completed.

But that’s just what we’re able to do now.

But ultimately, the test of whether or not we’re
producing useful information is going to be whether
or not people are actually using it, and so we’re
not letting ourselves off the hook for that. We
ultimately are going to be looking at that as well,
it’s just this is what we’re doing on the short-
term to be able to say something about usefulness.

So, for our second goal, we really have to
wait on this one, we can’t tell whether anybody’s
using our information until the information is
actually created for them to use. So, what we’ve
been doing here is focusing on once we have it, how
will we determine whether or not it’s being used and implemented.

So, we’ve been developing a set of indicators or metrics here. They start on the left hand side with very modest measures that initially are more about how effectively we’re disseminating than whether or not anybody’s actually taking the information up, and they -- toward the middle they become more and more reflective of whether anybody’s actually taking up the information and using it, and then at the far right, it really becomes a question of is this information actually being implemented and actually having an impact on decision making, on healthcare, and on health outcomes.

On the left hand side, these are all things that can readily be measured. There are some existing systems and data sources and ways of measuring this that we can take advantage of and it gets harder and harder. Some of these things we actually have to create and they will be resources
intensive for us to track, and then when we get to
the far right, really looking at impact. Those are
going to be very challenging kinds of metrics to
track and so we’re thinking that we try to do
everything on the left hand side for every study,
but maybe we focus in on a smaller set of studies
as we move toward the right.

And then finally our third goal, to
influence research, we had initially thought that
we would have to wait until we had something to
show for ourselves before we started influencing
people, but we’re already detecting that that’s not
ture, that people are very excited about patient-
centeredness, they’re very excited about
engagement, and we’re already starting to detect
some influence.

So, these turn out to be things that we
actually can start to measure now and we are trying
to put the systems and the means in place to track
some of these things.

We’re able to look at, for example, and
this was said earlier too, the extent to which people are being influenced by our methodology standards and things like whether or not they’re using the guidance that we put out about engagement or about patient-centeredness.

So, we think we will be able to tell you something about influence probably in the next quarter or two, definitely by the end of the year.

Finally, the third set of questions in the framework, the kind of all-embracing, all-encompassing set of questions go to the questions about our approach, the PCORI way. Does research done differently in fact make a difference, or what difference does it make? And these are some of the toughest and the most ambitious, but also the most important questions for us to be able to answer.

So, what we’ve done here, and it’s on the web, we didn’t put it in your binder or attempt to show it here because it’s 26 oversize pages long, but what it basically does is sort of -- for each ingredient in the PCORI recipe, it lays out a
diagram, for those of us who are visual, that kind of shows what our theory is about how that ingredient contributes to the total recipe, and then after that comes a table, like I showed you initially, that lays out what all the questions are. And it’s all -- it’s just questions, it’s all plain English, it’s straight forward questions about, you know, if we do this, will it result in that. If we take this approach, will it lead to that?

So, these are the sections in it. There is an entire section that focuses on engagement in research, but what you will find, because it’s such a key ingredient for PCORI, is that questions about engagement are also in all of the other sections.

So, what would really be helpful from you all is if you would adopt a section of the framework that particularly interests you and actually take a look at it and let us know whether or not you see your questions reflected in it so that we can be sure that we’re really capturing
what’s important.

This is the first draft that we’ve posted. We’ve had a lot of input but we’d like to be sure that we’re capturing all the questions and prioritizing them before we move on to tackling them.

So, on the really big question of what difference does engagement make, we actually have had quite a bit of activity underway, especially with respect to merit review. We’ve been looking at what difference engaging patients and other stakeholders in merit review had been making to that process and that work is ongoing and I believe that Joe presented it at a previous meeting and that we have a paper that was accepted and will be coming out soon on this.

We also are attempting to study what is the effect -- what are the early effects of engagement in research. And in order to do that, we really needed to have a way to capture and describe exactly what is going on with engagement
in our studies, and so we have developed this tool, we’re calling it the ENACT, which is a self-reported tool to measure and describe in very great detail what is actually going on with engagement in our funded projects, and we’ve developed slightly different versions of this tool for the pilot projects, the CER studies, and the PCORNet projects, because they have slightly different needs.

This tool has been in development for quite a while and it’s been pretty thoroughly tested and vetted and we think we’re ready to give it a try. So, it started off as something that we developed in the context of the Pilot Project Learning Network and it has been developed in close coordination with the Patient and Family Engagement Rubric.

So, it captures a lot, as I said, about engagement, who’s engaged, who are they, how are they forming these partnerships, to what degree or at what level are they being engaged, what are they
being engaged in, exactly, what are the effects
perceived by different members of the team on the
different aspects of the research process, what are
people to finding to be the challenges in the
facilitators, and what are people learning, and how
are they finding the PCOR principles to be
implemented or not.

So, what we’re hoping to do with this is
assess all of the studies that have -- when they
reach their 12-month point, and we have a bunch of
those now. And we think that at this phase we can
tell something about what the impact of engagement
has been on the formation of the research
questions, on the study design, on the functioning
of the study team, and perhaps on the earliest
phases of recruitment, and we hope to be able to
report that to you by the fourth quarter for this
first batch.

So, as I said, this is the blank table
that I showed you at the beginning, just filled in
for one of these engagement questions. So, what is
the effect of patient and stakeholder engagement on
the functioning of the study team and on the study
design? To figure this out, we need to be able to
measure with some precision what we mean by
engagement and what exactly is going on in the
studies.

And so, we’ve developed the ENACT. The
methods that we’ll be using will be a combination
of qualitative and quantitative ones and the
sources for this will be what we learn from
applying the ENACT tool, the progress reports that
the studies are required to submit every six
months, and the conversations that are had with the
study teams by both project and engagement
officers.

And we would love it if you would like to
know more and if you would like to help us out,
these are some of the things that you can check
into if you’re interested. One, we are blogging
about this as often as we can and we post the
materials that go with the PEG meetings also along
with these blogs. We have, as I said, now posted
the evaluation framework so you can take a look at
that.

We had also earlier posted the usefulness
criteria if you would like to comment on those and,
as always, you can comment on anything and
everything through the info@PCORI.org.

And I think that’s all she wrote.
CHAIRMAN NORQUIST: All right. Thanks,
Michele, and Joe will present the dashboard after
the break.

MS. ORZA: Correct

CHAIRMAN NORQUIST: So, we have time to
talk about just evaluation now. We’ll go
clockwise. Let’s start with Ellen.

MS. SIGAL: Do we have time for questions
now?

CHAIRMAN NORQUIST: Yeah. We're doing
this now and then we take a break and then we come
back and Joe does the dashboard, so we just want to
have comments on what Michele --
MS. SIGAL: So, thank you. It’s really useful. I like your evaluation criteria. I think it’s important because we really need to understand what engagement really does yield and what is different. But I’m a little perplexed about where you started from in terms of usefulness and impact. I mean, isn’t that really our criteria? Aren’t we funding everything based on its utility and its impact? Isn’t that a core value that we have?

So, I’m kind of confused. I’m not confused on the back end on how you’re going to evaluate and, you know, understanding the utility of the methodology and on the -- the patient-centered aspect, but isn’t that just core that everything that we fund should have -- should be useful and should have impact?

MS. ORZA: Absolutely, and I think that’s what we think -- we hope that we have captured through our topic prioritization process, through our merit criteria, through our methodology criteria. We hope that we have a process which
identifies and funds only studies that are likely
to yield useful information.

What we’re trying to figure out through
these usefulness criteria is whether we’ve missed
anything. So, in what other people are telling us
would be a useful study, is there some distinct --
something distinct there that isn’t already
captured in one of our merit review criteria or our
methodology criteria? And we’re kind of in the
middle of that analysis, so we’re not sure yet.

In other words, usefulness is maybe a
little bit different than impact or significance.

MS. SIGAL: We’re hoping to re-analyze our
criteria for funding on usefulness and impact,
because, again, those are core values, those are
core criteria, I would think, of anything that we
fund. So, we want to see if we missed it or we’re
not evaluating it or capturing it, is that it?

MS. ORZA: Yep.

DR. WEISMAN: One is intent and the other
one is what happened.
MS. SIGAL: For funding that would be -- I mean, if we go through the criteria of peer review and we’re funding something, theoretically we -- the potential for it to be useful in impact would have been there in the criteria?

It would be disappointing if we missed it.

CHAIRMAN NORQUIST: That’s a very good point. It will be very disappointing.

MS. ORZA: We will be very disappointed.

CHAIRMAN NORQUIST: Yeah, we’d better hope. Yeah. Okay, Harlan Weisman.

DR. WEISMAN: Harlan Weisman. Michele, thanks. It’s a great undertaking and I just in general really like the framework that you outlined.

I have two major comments. One is about not just developing the framework, which the working team has done, which as I understand it is internal except for two external people we’ve appointed to participate. But it’s largely a self-evaluation and I think the most useful information
often comes when you ask not only self-evaluation, but ask others on the outside to participate in the evaluation, you know, 360 type thing, and I’m wondering whether that’s been considered.

We talked about it at the Board about 18 months ago and one thing that externally people have commented on historically about PCORI is the question of whether we’re going too slow.

So, you mentioned, for example, that a lot of our studies -- you know, it’s premature for us to look at usefulness because we don’t have the results yet, but should we have the results? Should we have funded things that -- where we would have the results? And, in fact, if we looked at our portfolio, my guess is that many of the studies, and certainly when you look at that chart of dissemination, uptake, and impact -- many of these things will maybe not only outlive PCORI, but maybe PCORI Board members in terms of when those things can be measured.

That’s not bad. We should have something
-- an annuity of ongoing influence, but shouldn’t we also have things in which we have influence, you know, sometime in the next year or two? And that’s something I wonder about because I don’t know the answer to that question.

So, timeliness, to me, is a big deal and the idea of should we be getting external review as well as internal self-evaluation before the general -- the GAO does their thing?

And then one last -- more minor -- is we used to talk about -- I remember conversations with Joe about this. Usefulness is important, but so is usability. You know, if I find -- just as a trivial example -- I find often when I buy something and I look at the instruction manual, there’s probably a lot of useful information in there, but I can’t discern it, it’s not very usable, so I think both of those criteria are important.

MR. KUNTZ: Rick Kuntz, Board member. I want to essentially echo Harlan’s comment. I think
that what you have is a really good operation plan, it’s really good, but we probably ought to invest in having external review just basically re-gage, and I would probably recommend that what we do is just set the objectives of what you want to have them evaluate and let them figure out the methods to evaluate them, and the idea that Harlan said, the 360, I think it’s not what you want to do in your operational stage, you know, you were going to gauge your projects by what you’re doing by exactly what you’ve laid out here, but it would be good to get a biopsy from the outside.

CHAIRMAN NORQUIST: Alicia.

DR. FERNANDEZ: Thank you. Alicia Fernandez, Board member. This is a very lucid and such a thoughtful approach to laying out what the evaluation questions should be and how one could begin to approach them.

I wanted to come back to the evaluation of this question number three around patient engagement, which may be the most novel component
that PCORI has to date added to the large scientific research work. And it may simply be that I did not follow it completely, but I wanted to go back to the slide where you talk about the methods and the sources -- sorry, the slide number -- you got it -- and the reason I want to come back to this is, and I think it may be hidden in here, is we are asking the patients, right, and we are asking the stakeholders in the sources, not just the project and engagement officers, right? And I wonder whether there may be -- and I assume part of that is through this ENACT tool, but the reason I make this comment now is that the window may close on learning about all of the things that do not work as we go through them in real time, and I wonder, because this is such a novel component that PCORI is bringing and because there should be many ways that people are approaching this, I wonder whether the evaluation group has considered investing in a qualitative evaluation that is fairly granular in terms of following along some of
these projects, and doing so from not the
description of the project officer of the
scientific research team, but from an outside
description that can really interview all three
proximal stakeholders? I hope that was clear.

DR. FERNANDEZ: Helpful. Thank you.

CHAIRMAN NORQUIST: Joe, it’s your turn.

DR. SELBY: Joe Selby. So, I just wanted
to reemphasize this notion of -- two things, one,
the notion of usefulness. That’s a word that we
actually didn’t invent. I mean, patient-centered
we didn’t invent either, but patient-centeredness
with respect to research, we were just about the
first to talk about it, and now it’s -- everyone is
talking about patient-centeredness in research as
well as in care.

And I think usefulness we did not invent,
actually, the first place that I heard it was
developing a concept of usefulness. It came from
the National Health Council, Mark Boutin and others
at the National Health Council. We have been
working with them and I think Michele showed you a pretty advanced definition.

One of the characteristics of usefulness is it’s something you can assess at the level of the funded awards before the research is done, in one way, and then you assess it again when it’s completed, but I think we are -- this framework stakes quite a bit on a definition of usefulness that started externally, that actually we have compared notes with them and I think they feel like we have a very good handle on measuring usefulness, but it’s a metric that we would be well served, I think, to promote as well as to apply, and engage in debate and get perfected, because I think it’s going to become a byword and it would be nice if we were in the lead.

And I think that until you can show that you’ve got useful results, it’s better to be able to say that you’ve got useful research. I take Ellen’s point that everything we do should be useful by definition, but I think -- I really think
that the criterion that we’ve come up with is probably even a little bigger than what we asked applicants to come up with.

So, I do think it will be worth our measuring and it will be helpful to us, particularly until we get the results.

The second thing is this notion of an external evaluation. I don’t have any problem with that and I think we could commission one or encourage somebody else to just undertake one, but if we are a learning health system, we’re also going to be evaluating ourselves regularly and especially if we say that we’re at the cutting edge, I think we’re going to perhaps trust our own evaluations rather than those of others for a while. So, I think we really -- and the last thing to be said about that is that the engagement group really does bring in external expertise to go with the Board and Methodology Committee and staff. So, I think there’s -- probably we’re going to get more out of this internally than we would from most
external evaluations today.

CHAIRMAN NORQUIST: Okay. Bob Jesse?

DR. JESSE: Bob Jesse, Board. So, in the end, knowledge is information put to productive use. And as a final measure, that’s really what it comes down to, but I think everything else, and particularly process measures are informing, and in many respects, they’re going to be informing about both the fidelity of the work that we are doing or we are awarding contracts to do, meaning, are people doing what they said they were going to do and in the way they said, and also informing, I think, about the process of research, which then speaks to efficiency and value.

And so, there’s a lot of measures in here, but I think they all have a role, all are important, all will keep us well grounded, well poised, but in the end, the external evaluation is going to come around knowledge. Have we generated the knowledge that changes how healthcare is delivered in this country?
CHAIRMAN NORQUIST: Deb?

MS. BARKSDALE: Debra Barksdale, Board.

Since Joe brought up about the usefulness criteria, I did have a question about that particular slide. I was going to let it pass, but now I think it will -- I am curious about the use of the word “would” as a criteria, as opposed to “should” or “could”. Can you explain a little bit about -- I know it’s semantics, but words matter, so what -- and under the first bullet, “People who would use the information have been identified. People who would use the information are asking the right questions.” What does that mean?

MS. ORZA: This formulation of the criteria is to apply them to assess potential for usefulness. I’m not sure I understand the --

MS. BARKSDALE: Understand the question?

MS. ORZA: Yeah.

MS. BARKSDALE: People -- so, you have “People who would use the information have been identified.” So, I guess I don’t understand -- so,
you’re identifying people who would use the information as opposed to people who should use the information or could use the information?

MS. ORZA: So, the first three criteria relate to trying to establish whether or not the extent to which the idea for this study or the question underlying this study is user-driven. So, does it come from the people who would want this information or who need this information or who would use it if they had it? That’s the sense in which we --

DR. LEWIS-HALL: Can I take a run at this? I think I know where you’re going, which is, let’s take a group of primary care physicians that treat a certain population. These are people that should be applying this information. And your question is whether or not the ratio would be right if we only measure “would” use it. So, there are 100 physicians that should be applying this information in order to improve the outcomes of their patients. How can we measure, right, but only 20 would
according to this measurement. I think we want to close that gap. We want to say -- we want to measure who would against who should, not just who would.

I think I just made it worse.

[Laughter.]

MS. ORZA: It's kind of the -- sorry.

DR. LEVINE: Sharon Levine, Board member using thing microphone. I think to some extent I think the difference is that in some ways the way this is formulated, and by the way, I think this is right, is people who in an ideal world, because of the nature of their practice, would use this information, is what you’re trying to get at. The question of closing the gap between those who would and those who should is a different set of activities. It’s around dissemination, it’s around education, it’s around engagement of the clinicians.

But starting with identifying that population of either clinicians or patients who in
an ideal world would use that information, because it should be of high utility to them based on our best ability to estimate that, then we get to ask the question later of, okay, now that we’ve done that, how do we close the gap between those who should use it and those who are using it. Does that help?

CHAIRMAN NORQUIST: Maybe we have some more discussion to do on this one. For now --

DR. SELBY: Could I --

CHAIRMAN NORQUIST: -- I think a concrete example of where you have this might be much more helpful than the hypotheticals or something where you’d put this into place if we had an example of where you actually did an evaluation using this might be very helpful to make sure we’re addressing what the concerns are here.

DR. LEVINE: But to some extent you’re not going to -- I mean, the goal isn’t to have the universe of users drive this, it’s those whom you can identify who are situated in a way that they
would, should, could, and ought to need to use the information in order to get beyond that first question.

DR. DOUMA: I agree with Freda, a concrete example of how you would measure who would versus who should and what’s the difference, and just give us an example.

MS. ORZA: This first set of three, which is trying to get at the notion of whether this, you know, this question is being asked by the end users or whether this study is being sort of driven by the people who would want and who would use the results is a little bit different than the other two sets because it’s almost like it’s a scale, right? I mean, at a minimum, if you’re looking at an application, you would want the investigators to have clearly identified the users, the end users of this information.

And the third criteria we really think is the ideal, that this question, this study is really coming from the end users. So, that’s kind of the
sense in which we -- you know, you’re looking at an application and you’re trying to gauge how well they’ve convinced you that this is really a user-driven, that there’s a set of end users out there who are really wanting and waiting for this study, which will increase the likelihood that it gets used. That’s kind of what they’re driving at.

CHAIRMAN NORQUIST: So, yeah.

DR. DOUMA: While we're on semantics, the real word -- the clear answer, I think it’s important that we have the concept of oftentimes we won’t ever have a clear answer in our lifetimes and that decision making is based on unclear information but it still may be useful, and we don’t want to throw out the baby with the bathwater.

CHAIRMAN NORQUIST: So now that we’ve had all our semantic games, I think it’s time for a break. My brain is gone at this point. So, let’s do this, let’s take a break. I’m sorry, Francis, did you want to say -- did you have your card up?
Yes, it’s now up. Okay, go ahead.

DR. COLLINS: I’m just thinking, anybody who is listening to this discussion on the phone must have wondered what they’d walked into if they just tuned in the last ten minutes and we got into “coulda, woulda, shoulda,” in a way that I’ve never quite heard debated before. It’s really fascinating.

I just wanted to enter the colloquy between Rick and Joe about who does the evaluation on the side of both, and, instead of either/or, and maybe that’s what you’re both saying.

I do think PCORI is in a great position to be able to do its own evaluation and must do so. If I have any concerns about the plan that’s put forward here it may be that it’s even a little over-engineered and you have to be careful not to lose the forest for all the trees that you’re going to be cataloguing.

But I do think for credibility on the outside, and for other reasons of getting a fresh
perspective from people who don’t have some particular reason to want it to look good and we all probably have some of that, if we’re honest with ourselves, you need to have that outside look as well.

And GAO will do some of that, but you don’t want to depend on GAO to be your only outside evaluator.

CHAIRMAN NORQUIST: I think you’re absolutely right and we should think about what that -- certainly not as comprehensive as what we’re doing or something like this.

So, we’ll revisit this, I’m sure, some more, and as we get more concrete examples, it will help us do the semantics, I think, to some degree.

So, let’s take -- we have a 15- minute break, which brings us back -- well, probably at 3:30 is the way we usually operate. So, we’ll be back at 3:30.

[Recess.]

DR. NORQUIST: Okay, we are getting ready
to start back up again. We will now restart our afternoon session and we’re going to pick up with Dr. Selby who is going to present the actual dashboard. So, those slides should be coming up.

Are you going to sit here and do it?

DR. SELBY: That’s right.

CHAIRMAN NORQUIST: I’m fine. Yes.

DR. SELBY: So, thanks, Gray. This is Joe Selby and I’m just going to put this up just so you can feast your eyes on it and make some introductory comments.

This is the first time we’ve shown a dashboard like this to you. Up until this point we’ve shown you a dashboard of one-offs, things that have to happen and have they happened, so that was the 2013 dashboard.

If you notice on this, you see a lot of arrows moving from left to right, you see some trends over time, so the dashboard from now on is going to be a longitudinal instrument to show you changes over time and hopefully progress.
I don’t have any doubt that after I get finished with this presentation you’re going to suggest that some items on this dashboard are really not very informational and don’t need to be continued, you can save the real estate. And I hope that you’ll also, working with us today and as we go forward every quarter looking at this updated report that you’ll -- that we together will come up with other metrics that better reflect what we think is meaningful progress. And so that after two or three quarters of looking at this, this will become a document that we all know and if we don’t love it, at least we’ll understand it and be able to spot changes as they happen over time.

The last thing to say is that there are several items on here that are still in development and I’ll point those out as we get to them.

And then I also have some slides behind these that back this up, but I will try, starting in the upper left, to introduce you to this dashboard and what’s on it and I have a better
slide than this one. The upper left most graphic shows you it’s all in percents so by cycle three, there are four vertical bars and they are from left to right. The applications, as a percent of LOIs, so you’ll recall that we always get about 40 percent of our LOIs turn into applications, and that’s pretty steady over time. Maybe it’s going up a little bit in the most recent -- the August and then winter 2013 applications.

The next bar is the awards as a percent of applications, so that’s basically the pay line, and you’ll recall that it was down around 5 percent in the very first cycle, but after that it’s been between 10 and 11 percent and that’s where it has stayed as far as we can see, which is through the August 2013 award cycle. The others, we don’t have the awards yet.

So, the pay line remains about 10 percent. The third bar, and it only kicks in in cycle three, is resubmissions. So, the light blue is resubmissions as a percent of the total number of

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applications and you’ll see that each time that
looks like it was about 10 to 15 percent of the
applications were resubmits. And the fourth bar,
the bright purple bar, shows that both times the
resubmissions did much better than the overall pool
of applications.

Moving down then, and I hope you can see
this better than I can, it seems like the focus is
off or else my glasses are, the next one, and I
don’t think we have a slide that shows this, the
next one is the priority topics. So, these are
targeted PFAs and other high priority items that
are sent to the pragmatic clinical studies
announcement.

So, a total of 40+ high priority topics
have been processed and identified, either by the
Board initially, or subsequently by the advisory
panels. Fifteen of those made their way onto the
list of the pragmatic clinical studies and I showed
you the results of the first solicitation from
that, and under the column called “funded”, none of
those have been funded. The first funding will be in January of 2015 after the reviews in November.

Then the targeted PFAs, we have three targeted PFAs that have been funded and those are the prevention of falls in the elderly -- and when we say funded we mean the funding has been transferred to NIA, and by the way, we’re just about to announce the awardee of that and we will certainly let you know with great detail when that is announced -- and the second one are the asthma awards that Romana reviewed a little bit ago. And third -- under the asthma targeted PFA -- and the third is the uterine fibroids targeted PFA, and that announcement is still a bit away. The reviews have been done, but the announcement is not quite ready.

And then the three others that Romana also told you about that I think at least two of those, the treatment of obesity in high-risk populations, there’s one for improving health systems on transitions in care, and the third one that has
been approved, I believe, is the -- yes, the blood pressure control in minority populations. So, those are the other three targeted PFAs that have been approved by the Board and are in development.

DR. DOUMA: Joe?

DR. SELBY: Yes.

DR. DOUMA: I’ve got a clarification. There you have posted under targeted PFAs three -- funded three of six? Do you mean posted as six and we’ve funded three of them?

DR. SELBY: And I should have said at the beginning that I’ve got Michele right behind me and sometimes I’m going to have to lean on Michele a little bit for some of these details. So, Michele, could you just address exactly the posted? I think you’re behind me, aren’t you?

MS. ORZA: [Off microphone.]

DR. SELBY: Okay, so that would be obesity --

DR. DOUMA: So, I’m just clarifying --

once something that is posted as funded, it comes
off the posted --

MS. ORZA: Correct.

DR. SELBY: What’s the third one? I mentioned transitions in care --

MS. ORZA: Promise.

DR. SELBY: Pardon?

MS. ORZA: Promise.

DR. SELBY: Oh. Okay, the Promise Awards. Below that is a measure that we’ve just discussed in detail, the usefulness, so by quarter four of this year, so by the end of September this year, we will report to you on the usefulness using the criteria that we’re developing in our portfolio.

We will also have early measures of engagement impact by that time. So, those two need some more development and then they particularly need measurement within the awards.

DR. WEISMAN: What would that be, though, because I thought Michele said it was very difficult to do these before we actually have the research?
DR. SELBY: No. We have, as I meant to say earlier, usefulness is a concept that we feel we can assess at the application level or at the award level, so I think -- at the award level, so this would be usefulness among projects that we’ve awarded. So, you know, we have usefulness built into the merit review process and we would hope, as Ellen said, we would hope that what we wind up funding does indeed meet usefulness criteria. These criteria, as I said, were contributed to by people including ourselves, so others have weighed in too, we need to really promote the meaning and measurement of usefulness and then apply it to our portfolio just to give us a better sense that we’re on the way to useful results.

Engagement impact is the same, and then beneath that is the first of several arrows that you’ll need to get a little bit use to seeing. This is our commitment of research funding thus far. So, the far right, you’ll recall that in lengthy discussions in, I think it was September,
when we were contemplating the 2014 budget, we talked about committing $528 million this year and we converted that to committing a billion dollars over two years at Dr. Goertz's advice.

The news is that if you look on a quarter-by-quarter projection, we’re currently at or very slightly ahead of where we aimed to be at this point, but the big news is that by the end of the fourth quarter, we will not be at $528 million. So, Christine was absolutely right, and those who agreed with her, and so you will see that next quarter, and particularly at the end of the fourth quarter, we will have funded a lot -- we will have committed to funding a lot of research. We don’t think, at this point, it’s going to come to $528 million, but it will be in the $400+ million range for this year.

Okay, so that’s -- I’m going to go to the middle column now, the top bar, and this is a question that the Board is asked a lot and I put it up to you whether this is something you want to
continue monitoring over time or possibly do something about.

So, this shows you the proportion of our awards subtracting out the methods awards, the proportion that are prevention, that’s on the bottom, the light green, diagnosis, that’s the dark blue and that’s a very slender sliver of the total, the light blue, which is treatment, so most of what we evaluate is treatment -- most of what we’ve funded is treatment, the green is screening and then the other is kind of a composite, I think.

So, it really does not show much change over time, perhaps a little bit of a drift up in topics other than treatment, but I’m not sure that it’s at all meaningful, and I would just invite the Board to -- now having seen it for five cycles -- oh, I’m sorry, the last one is the total, so there’s really only four cycles there -- having seen it for four cycles, it does look like there’s a little bit of a drifting up, and whether this is something worth following over time or worth doing
something about, either one of those, I think, is a legitimate response. I mean, are we underfunding in some area in way that you’d like to see us change?

The next is the progress of projects from the first -- from quarters one, two, and three, so we have evaluated --

UNIDENTIFIED: [Off microphone.]

DR. SELBY: Let’s see if I do here. Okay, so this is what we’ve just been talking about. So, you see the light blue is treatment, the dark blue is diagnosis, the light green is prevention -- this is an “all” column here, so these are the ones you want to look at, this is if you want to look for a trend, and if anything, this light blue is shrinking a little bit over time, but I don’t know at all that’s an important change.

This next one is progress of projects, shows the results of our program officers monitoring the projects to see if they’re hitting their milestones, and I have a slide later on about
this, but you’ll see that at the -- for research, so this is -- all the projects that are at six months, and there may be a few that are at 12 months, and Michele, correct me if I’m wrong, but this is the proportion that -- oh, I see, this is two quarters, I guess -- quarter one and quarter two of the research projects, of their life. So, 67 percent of projects were in compliance at the end of quarter one and 63 at the end of quarter two, and we do have a detailed slide coming up on that and this is obviously something we’ll want to follow closely over time.

I’m going to move over to this little table up here in the upper right. So, there’s only one number on here, and this is a learning experience that these just don’t project very well. The application adherence to the methodology standards. So, this is specifically adherence to the methodology standards. And as Bryan explained this morning, we’ve really only looked at one quarter’s worth of one round, the most recent round
where they were really expected to adhere, and we found that 74 percent overall, at the initial assessment, these were corrected before they were funded, but at the initial assessment, 74 percent adhered to the methodology standards using our template, and I’ve got a slide on that.

UNIDENTIFIED: Quick question.

DR. SELBY: Yes.

UNIDENTIFIED: [Off microphone.]

DR. SELBY: Good. This is the new fiscal year. So, the second quarter ended in the end of March.

Okay, so the next is from our engagement program, how we’re doing with respect to the Pipeline to Proposals awards. And this shows that our planning called for us to be at this point here and we’re just a little bit ahead in terms of the amount of funding we’ve awarded, but the planning also says that by quarter three we’ll be much further than we are now.

So, this is about 31 projects funded and
we’re proposing to fund 65 within the fiscal year, and they should be funded by the end of the third quarter, so we will see the next time we report whether we stay -- whether we’ve actually got this green dot moved out to here, whether we are up to staying up with our plan. But for the moment we’re on schedule there. Yes?

MS. HUNT: Gail Hunt. Is that the awards -- so, that’s the Tiers 1, 2 and 3 --

DR. SELBY: Yes.

MS. HUNT: Is that just the awards or are those the ones that have done well enough to now be putting in a real proposal, which would be there’s the point, it’s not just how many awards you gave out, but are they -- did they move on to be able to apply?

DR. SELBY: Right, and I think that’s a metric that we will have -- that’s a metric that we will have but we don’t have it yet. This is just the number, but it’s a very good point.

MS. HUNT: I would say that would be more
valuable to have in -- sooner.

DR. SELBY: Yes. Okay. The next is the result of surveys from four events, and I think over time we’re going to need a better way of presenting this and, in fact, I believe I have another slide that gives you -- so, the key point to remember about this, too, is when you get this packet -- when you get this report, you always get a set of slides that back it up and there is a slide that will detail this, but 86 percent of participants in any of, I believe, it’s four engagement events say that they have done something new with patient-centered outcomes research since they participated in the workshop.

This is the ambassador training, and that’s actually -- you see that by quarter three we’re supposed to have 50 percent and 50 ambassadors trained. We were not supposed to have any trained yet by the end of quarter two and that’s where we are. I think that we will -- I think we’re planning to hit that mark. I’m not 100
percent sure, but you’ll see at the end of the third quarter if we have.

So, just moving right below, the completion of phase one of PCORNet looks like it is a little bit behind and that is only because -- remember, PCORNet just started in quarter two of 2014 and our goal for the end of quarter one was to have all the contracts signed. We fell just a little bit short of that. All the contracts are now signed and that’s because these contracts were extraordinarily complex and they were new, they were new to us and they were new to the awardees, so it took an amazing amount of work on the part of our general counsel Mary Regina and our contracts group, especially Scott Solomon.

So, they worked night and day, as, I think it’s fair to say that folks in program offices around the country who were the awardees worked hard too, but I know that we bent over backwards to make this happen, and refined the contracts somewhat in the process, learn from it, but that
was a lot of work. We have caught up, but that was a lag and you’ll see it reflected below, but that’s also why that’s got a yellow title there, yellow heading. Yellow means that we are off track to some extent.

Just for the moment going down right below that to speak to staffing, and Regina is going to speak in the next presentation to both staffing and expenditures, but you will see that we are actually behind even our quarter one projection. So, we had extraordinarily ambitious projections to be at 165 by the end of the year and nearly there by the end of the first quarter.

So, we were at 118 at the end of second quarter and we are now up in the 120-some where we are hiring at a pretty steady pace and we’ve talked a lot this morning about -- in the -- where was that -- I can’t remember exactly where we were having this discussion, but doing a lot to orient these folks and to get them plugged into the PCORI system.
But we are behind, more behind the second quarter, and I think we will still be behind at the third quarter, but I predict -- and it looks for all the world like we will be at 165 by the end of the year.

Partly as a consequence of the delays in staffing and partly as a consequence of delays in submission by awardees of invoices, we are well behind in spending too, but Regina will go into much detail with you on that.

So, I just want to point over here. Communications, I’ve got a slide a little bit later on that shows that we are continuing to be well above our expected goals in various aspects of communications. Journal articles by and about -- and seriously about PCORI are accumulating. And media mentions certainly are there.

The red one, the award to contract time, last time we were very pleased to announce that we had gone from 16 percent of contracts awarded within 90 days to 80 percent. We’ve dropped to 37
percent but I’ll show you some data in a minute that nearly all of this is because of those 29 CDRN and PPRN contracts, which just took much longer because they were first time and they were very distinctive.

Contracts response time remains remarkable, in fact, it’s a little better even and 99 percent are answered within two business days. And the science response time on the very bottom has risen from 54 percent two quarters ago to 81 percent answered within three days, and this is, I think, due to diligence on the part of staff but also, it must be said, some growth in the staff, so the capacity has improved.

DR. DOUMA: Joe?

DR. SELBY: Yes.

DR. DOUMA: On the communications side, you’re talking about the industry click-through rate?

DR. SELBY: Yes.

DR. DOUMA: I saw this earlier and so
maybe I’m misreading it now. Is that saying it’s like 140 and 130 and 140? Those are the three numbers? Anybody else can see --

DR. SELBY: Yes, it’s 140 percent of the target or the reference.

DR. DOUMA: Oh.

DR. SELBY: And on the first one, the unique web visitors, the target was the same quarter a year ago, so we are 50 percent ahead. We’ve grown by 50 percent from last year.

The next one, though, the target is the industry standard for the click-through rate and we are 143 percent of that.

DR. DOUMA: Okay. Yeah, I was reading that as your click-through rate was 140 percent and I thought that was really ingenious --

DR. SELBY: That’s right.

MR. KUNTZ: Joe. I’m a little bit bothered by the one in expenditures, and I think that’s an indicator of are we doing our job, and I just wonder why you’re not using the accrual
system, meaning you’ve got outstanding invoices, we
should probably put the expenses accrued rather
than --

DR. SELBY: Can we defer that to Regina’s
presentation? She’s -- and she’ll have Pam right
behind her, to respond to that. I appreciate the
comment.

Now I’m going to go kind of quickly
through -- this is basically the same information.
Now it’s presented in numbers instead of percent,
so the percents don’t quite let you know that the
number of LOIs is pretty steady. It’s gone up a
little bit but in part because we’re sometimes
tucking additional opportunities into the number of
applications received. But there’s nothing else
new on here I don’t think, a little bit new -- the
details on the asthma and the infrastructure awards
over there.

And this is, again, the composition of the
portfolio in terms of -- this is 169 applications,
the methods are excluded, this is the first four
cycles, and you see that 74 percent of our awards are in the area of treatment, two percent in the area of diagnostics, so I welcome any comment and also the comment on whether we should keep following this.

DR. COLLINS: So, what should it be?

DR. SELBY: That's for you to answer.

MR. KUNTZ: But we should have objectives on these, right, so we can actually measure whether we’re meeting objectives.

DR. SELBY: It would be -- again, I’m putting it out there as a matter of discussion. I would be very interested on the Board’s opinion on, you know, I think that’s the same question, metrics on it or having --

MR. KUNTZ: And the slide before as well. I mean, I think it would be great to know whether or not we are --

DR. SELBY: You mean this one?

MR. KUNTZ: Yeah, what’s our target --

DR. WEISMAN: The whole issue of
diagnostics is a tough -- being somebody who was in
the diagnostics business once. It’s said that they
contribute up to about 70 percent of all medical
decisions and account for 2 percent of expenditures
and so it’s by coincidence, that’s what we’re
spending too on research. It’s tough because they
contribute a lot, but nobody wants to pay for them
and how we figure that out and their use and
appropriateness has always been a challenge.

DR. SELBY: I mean, it’s interesting to
think about the possibility of a targeted funding
announcement in that area. Diagnostics.

DR. DOUMA: Also, self-care and self-
management, the parameters that we looked at
earlier in the disparities arena cut across those
things.

DR. SELBY: Yes.

DR. DOUMA: So, I think we need another
circle somewhere.

DR. SELBY: Maybe not too much in
diagnosis.
DR. LEVINE: Just a clarifying question.

Sharon Levine. When you say -- I assumed diagnosis was different than diagnostics?

DR. SELBY: Well, diagnosis means, in this case, studies of how to make diagnoses, diagnostics, so I’m quite sure that this is diagnostic testing. I don’t know what diagnosis would be as a --

DR. LEVINE: Okay, but --

DR. SELBY: -- as a counterpart to prevention and treatment.

DR. LEVINE: So, diagnostic testing is -- diagnostics, at this point, is a term of art referring to a specific --

CHAIRMAN NORQUIST: Wait, Bryan Luce can tell us back here. What is it?

MR. LUCE: It’s definitely diagnostic.

DR. SELBY: Meaning comparative effectiveness evaluations of diagnostics.

CHAIRMAN NORQUIST: Okay, processes or technologies.
DR. LEVINE: But not just technologies?
Okay.
CHAIRMAN NORQUIST: Not just technologies.
That’s correct.

DR. WEISMAN: Just for clarification, and
I missed -- what I was taking about was in vitro
diagnostics, not the imaging and --

DR. SELBY: I’m sure most of this is --
very little of it is in vitro. There might be one
or two genetic testing studies, at the most --

CHAIRMAN NORQUIST: But we can dance
around this one, I think we can go back to the
question that Francis raised earlier, which is what
is the percentage -- who cares what --

DR. SELBY: Please.

CHAIRMAN NORQUIST: I mean, the issue is
we haven’t had that discussion about what is the
right number here. I don’t know what the right
number is, quite honestly.

UNIDENTIFIED: There are certainly
arguments to be made that we’re under-supporting
prevention when we all would agree that the healthcare system in general has been poor in defining effective means of prevention and we have a sick care system instead of a healthcare system. This seems not to be making a big change in that emphasis.

CHAIRMAN NORQUIST: Yeah, I would agree with you. I think the prevention field would look at this and say, you’re way under where you need to be on that.

DR. WEISMAN: It does reflect -- the overall pie reflects an emphasizes on disease management as opposed to health and, you know, we always talk about healthcare but we’re really talking about disease management and that looks like what we’re doing as well.

CHAIRMAN NORQUIST: But to me this is informative in the sense that it means that if we’re going to start targeting certain areas or we want to -- maybe prevention topics are ones that we should really look at as rising to a high priority
or something.

DR. SELBY: Okay. Just wanted to show you the comparison of the funding level announced with the funding level awarded, and so that’s -- after the first cycle, where we announced, I think -- well, it looks like we announced up to 120 million and only funded 40 million, you recall that first round we only funded about 5 percent of awards and really the judgment was that that was about the percentage that we’re ready for funding and part of the fall down was around engagement and patient-centeredness, and our judgment was that that improved every cycle since.

And so we funded about as much as we said or even in the case of asthma and infrastructure we funded significantly more than we put on the table because, again, we were very impressed by the quality of the applications. Can’t say it for those others yet.

UNIDENTIFIED: Joe, on the last slide, what’s the difference between prevention and
screening?

DR. SELBY: Well, to get technical, screening is looking for early disease often time, so it’s preventing bad disease. But, for example, in colorectal cancer or mammography, the cancer, or at least a precursor, has to be there and you find it with prevention -- with screening. Prevention would try to make sure that that cancer never develops in the first place, so that would be exercise or diet or vitamin or something along those lines.

DR. WEISMAN: So, what you’re saying is normally primary prevention --

DR. SELBY: Pardon?

DR. WEISMAN: It’s only primary prevention you’re saying because there’s the secondary prevention certainly flips over into what they were talking about.

DR. SELBY: I don’t know -- I do not know where secondary prevention came in, but even in the secondary case, you can still talk about screening
in the secondary case. Surveillance is a big part of that.

DR. WEISMAN: You’re right.

DR. SELBY: So, I do not know if -- I don’t know if you know, Bryan or Michele, whether secondary prevention made it into the prevention slice?

MR. LUCE: I can’t tell you that. I don’t know.

DR. SELBY: Okay, so -- and this just makes the point about the slowness, the decline from 80 percent of contracts signed within three months to 37 percent, so included in the 82 awards the most recent time where the 39 from the CRNs and the PPRNs, these were novel and complex and big. We executed 41 percent of them within 90 days and to date all but one, which is pending signature, have been executed. So, we really got them done in a surprisingly short time compared to the experiences, you know, in other large studies from other funders thanks, again, I’ll say this, to the
hard work of Mary and the contracts people. Just, you know, it was hard.

But once we started working on the other awards, that is the eight targeted asthma PFAs, asthma studies from the PFA and the 45 from the broad announcement, 70 percent of them were, nonetheless, executed within 90 days, so I think part of the drop from 80 to 70 was a diversion of effort to the CDRNs and PPRNs. But I think we have every reason to think that this high rate of 80 percent is what we’ll see going forward.

Science response time. Just thanks to the science team, congratulations, and yes, there’s still a little ways to go, but this is -- particularly the target is response within three business days and this response is usually by way of a nice conversation.

This is adherence to methodology standards, more information on adherence to methodology standards. Our judgment was that -- so, this is the cycle three awards, so this is
based on 53 most recent awards, those awards who really had to be accountable to methodology standards before they could be contracted, so there were four sets of standards, which are sort of applicable to every single application that we have, at least nearly all of them at the time of application, so we just present data on these four sets of standards. Overall the adherence to these four were 74 percent. Formulating the research questions, almost everybody got that right. Being patient-centered, not surprising that of those that were scored well by the merit review process, they got it right. Data integrity and rigorous analysis, so, this is really the analytic methods, a little bit of a fall off. And then dealing with this issue of the heterogeneity of treatment effect, which we tell everybody that they should do, and we have methodology standards for how to do it, less than half of them have met that one. So, that’s one that really needs some work.

But I want to hasten to add that before
these contracts were signed, and I think they’re all signed now, these deficiencies were remedied.

MR. KUNTZ: You know, this is a really important metric we’re following and obviously I think that it probably is one of the most important contributions we can make is to improve the rigor. Do you think the binary scale of whether they adhere or not is too overly simplistic and that maybe it should be a more scaled approach? Because I’d have a hard time trying to figure out who’s figuring out if we’re, in fact, adhering or not adhering to patient-centeredness, for example, and it just might be easier to gauge progress?

DR. SELBY: Yes. To create a score of some kind?

MR. KUNTZ: Yeah, I just think that they’d be tough to do as a binary.

DR. SELBY: Let’s take that under advisement. I know Michele is getting notes and it’s a good question, especially as we talk about this ENACT tool and I think, you know, we don’t
want to stray beyond the standards in the methods.

We do stray in what we talk to them about when we talk about engagement, for example, and we actually probably go further than the methods when we talk to them about what we mean by patient-centeredness, but --

MR. KUNTZ: [Unintelligible] is that you might have to resolve it to something simple like do they mention that they’re going to use a method and then that’s a yes, but really it should be something like do they mention it as a method and did they actually describe their method.

DR. SELBY: Yep.

MR. KUNTZ: I mean, there might be something -- there may be something that’s a little bit more granular than just yes or no on something so important like are we basically driving methods into research.

DR. SELBY: That’s a very -- we will get back to the Board on that because I think that’s a nice example of the Board improving the metric and
understanding the score that results as well.

Thanks, Rick. Larry?

MR. BECKER: So, Larry Becker. So, is there any evidence or process that says, so we’ve created these methodology standards that anybody else is considering them or using them beyond the things that we are funding?

DR. SELBY: Michele, if you can help me out here. I think we are on the lookout for that, but it’s not on the dashboard yet. Is that right?

MS. ORZA: That’s correct.

DR. SELBY: Okay, so, Larry, we will continue developing an approach to -- I know we are -- we do want to measure that and it will make it onto the dashboard at some point soon.

Okay, Ellen, it sounds like you’re in response to Larry’s question, otherwise --

MS. SIGAL: I think Larry brings up something really important --

CHAIRMAN NORQUIST: Ellen Sigal.

MS. SIGAL: -- I mean, yes, Ellen Sigal.
I’m sorry. If we pay for it, they’ll do it, but we want them to do it because it’s important ultimately and that the methods and the outcome is really important.

I know I struggle a lot with patient-reported outcomes and some issues that we don’t see nearly enough in clinical trials, but what we find is if you don’t require it, it doesn’t happen. So, I mean, I think hopefully our value is going to be that it happens not just because we’re paying for it and because it’s important to us, but because it’s important research and we get better results.

DR. SELBY: Bob? I think we’re done with the slides. Go ahead, Bob.

DR. ZWOLAK: Bob Zwolak, Board. So, my question goes back to your original dashboard and I was just looking back here and we announced the pilot projects late in 2011 and I think funded them in 2012, and so I see journal articles way down there in the bottom left and I assume those are articles about PCORI or authored by PCORI of
primary folks but not the results of our pilot projects. And my question is, when -- is 2014 too soon to start adding a metric of research reports, journal articles, written by authors funded by PCORI grants, because it seems to me that’s a huge metric of funding research and is it time to put that up there yet?

DR. SELBY: I think the answer is yes. We are aware of -- at that meeting that I called the sort of clandestine first annual meeting of PCORI, we became aware of several papers that were just about to be published. We also have two papers that were recently in the Annals of Internal Medicine that came from basically topic briefs or landscape reviews that we commissioned for the advisory panels. So, from Duke came a very nice summary of the evidence around ductal carcinoma in situ and a second topic, which I’m not going to remember right now. Bill might remember.

So, yes, there are some, excellent point, and we can definitely call out a category.
DR. ZWOLAK: I mean, I just think that’s hugely important and shouldn’t be buried down there with clicks on the website and emails and those sorts of things.

DR. SELBY: Good. Good point. Okay, I’m going to --

MS. NEWHOUSE: Can I just ask a question about --

CHAIRMAN NORQUIST: Robin.

MS. NEWHOUSE: Robin Newhouse. Is there a requirement for those funded by PCORI to publish within six months after --

DR. SELBY: That is -- you can’t require somebody to publish within six months because, as you know, sometimes it takes longer than that to convince the peers that it deserves publishing and get it into print, but we are working very hard and we owe you, in short order, a process, actually, for posting reports on completed work within 90 days of the completion.

So, you will get that -- we have a pretty
-- we need to discuss it first with the SOC and then bring it to the Board, but we’ve been working -- we’ve involved Hal Sox in the work coming up with a plan that we think will meet two requirements, the one is for a peer review process for everything that we fund to make sure that it adheres to the methodology standards, and the other is to get it published within 90 days. So, it’s complex to do both, it’s hard to do both a peer review and published in 90 days, but we’ve got a -- we have a plan that we will be presenting shortly. And, in fact, this has to go out for public comment, so this will be happening in the next month or two.

How much time do I have, Gray?

CHAIRMAN NORQUIST: Well, you’re over by five minutes.

DR. SELBY: I think I should just -- I don’t even know that I really need to -- I don’t think I need to say anything about that. It looks like we’re not going to have anymore Pipelines to
Proposals — nothing expected from Pipeline in fiscal year 2014.

CHAIRMAN NORQUIST: Incorrect slide, move on.

DR. SELBY: So, never mind. So, this is the engagement event survey details. So, interviewing people after four events, and you see the events down there, their response rate’s in the middle, and the summary question was -- where’s the question? -- since attending the workshop have you done anything new to conduct, promote, or use patient-centered research? And you see that the vast majority of people at each point in time said yes, and it shows the example up there in the italics but I’m going to move on.

Engagement events survey results -- so, this just shows two ways, either acted as a patient or stakeholder partner on a research team or acted as a primary or co-investigator on a research team and actually the higher percentages are acted as a primary or co-investigator on a research team.
And then this is the last slide, I think, and it’s on communications, and this shows unique traffic and there it is in numbers on the left, the target in green, the blue is actual, and on the right is three years -- those three squiggly lines are 2012, ’13 and ’14 -- ’14 is very short -- and it just shows that year-on-year we’ve had a big increase in traffic.

This is the Twitter follower group. This is email open rate compared to last year. So, you’ll see that we’re ahead of last year each time. And then this is the click-through rate, and this is compared to the industry standard, so we’re well ahead of that. And this is the media coverage that we’ve discussed.

So, that’s it and I thank you for your attention.

CHAIRMAN NORQUIST: Gail is first.

MS. HUNT: Gail Hunt, Board. You know, if we could go back to the dashboard? I would suggest that right now, progress of projects, needing
[inaudible]. I think that’s really not useful.
You were looking for things that might be taken
off, because -- the one right in the middle --
because at this point we don’t have any idea, like,
what that means. What is it, like they met the --
you know, it’s just so vague and so un-revealing, I
guess, of what we’re trying to figure out and we’ve
only got that one, you know, the research side.
What does it mean that -- I just think that it
would be -- you’re looking for gearing up things, I
would take that off.

DR. SELBY: Okay, so that’s a good point
and if we do leave it on, we better give you a very
detailed explanation on what it means.

CHAIRMAN NORQUIST: Yeah. Harlan Weisman?
We’ll go to Robin, okay. Robin Newhouse.

MS. NEWHOUSE: I just wanted to respond to
Gail. This is Robin Newhouse. The progress of
research, I actually -- my eye went there first
because a third of our projects aren’t on track, so
figuring out what the issues are is really
important for us to help other investigators that are being funded, whether it’s IRB approval or whether it’s the contract negotiations, it tells us there’s a problem in the process or there’s a problem with the implementation of the study.

If we can discover what the major issues are, and I know that people get to the end of their projects and they will be asking for a no-cost extension, which I’m not sure if we do or not, but to keep people on track, and a third are behind, is really important. So, defining that metric is an important one for us.

CHAIRMAN NORQUIST: Agreed, yes. So, I think the key issue is what does it mean and it could mean that they’re not even getting any subjects, which is a huge issue and then you really have to address that issue or it could just be the contract, I mean, so it does -- but if you aggregate it, what does it mean? Right? Okay.

DR. WEISMAN: Yeah, I wanted to go back to the comments on publications, which, you know, we
have this whole thing on open science and transparency, we also have an obligation of public reporting within a certain period after completion of the research, and then the investigators certainly want to write the publication.

But what I’m wondering is, what is PCORI’s responsibility on the publication of results that in the traditional sense an investigator feels they own it, they interpret -- analyze, interpret, report, and their emphasis or their findings may be different -- I’m not saying wrong, but may be different than what PCORI’s is as it relates to what PCORI’s mission is in terms of providing the information that enhances the ability of patients and clinicians and consumers to make decisions.

So, I’m not sure whether the standards -- how the standard approach works in conjunction with our obligations.

DR. SELBY: You know, that’s an excellent question and one we’re worried about with respect to this peer review requirement and the publishing
of results within 90 days, so we have talked about it a lot. I think it will come up when we present this plan to the Board -- to the SOC and then the Board, I think the short answer is that early on while we’re still close to the funding period, we will have some leverage over the investigators to show us their draft manuscripts or at least their final report and we’ll be able to peer review it.

Further out it’s going to be more difficult and I think other funding agencies also have a harder time following things once the funding has ended, but as the stream of publications keeps coming in we will have to find ways to do that and to register objections if we object.

CHAIRMAN NORQUIST: Larry, is your card up new or is that left over? Okay. Others?

One thing I would say is that one of the ways you can get people to publish quickly is to give a deadline on when their data or their priority and then when they become public, so if
you’re very clear that the data are publicly
available at some point in time that others can
analyze, they’ll quickly get their papers out.
Trust me. I mean, that’s the lesson that’s already
been learned.

DR. SELBY: And that is part of the plan.

CHAIRMAN NORQUIST: Okay, yeah, and that’s
part of our open science issue, I hope, is the part
of that discussion.

Okay, thanks. Any other questions? All
right, thanks very much, and as usual, we’re asking
for continued feedback on how to improve this
dashboard and I think we’ve had a number of
suggestions today that could be very helpful.

Okay, Regina? I hope we’re going to be
able to move because we are coming up against our
public comment period. So, what do you want to
present first, this resolution for a cash-secured
letter of credit, I mean, which is a big issue but
relatively minor for the Board, but we have to vote
on it. Do you want to do that first?
MS. YAN: Yes.

CHAIRMAN NORQUIST: Okay, so let’s skip through that one pretty quick. And everyone should have some --

MS. YAN: Yes. You have the hard copy in front of you. It was also sent ahead of time electronically.

We have funds in our 2014 approved budget to lease additional office space to accommodate the additional new employees we’re bringing on board. We have already signed a lease on M Street for additional office space, which is only one block away from our current office on L Street and the lease requires a Letter of Credit of $150,000 as a form of security deposit and the Letter of Credit will require the Board’s approval.

CHAIRMAN NORQUIST: So, we just need a motion to approve --

UNIDENTIFIED: I so move.

CHAIRMAN NORQUIST: Thank you.

UNIDENTIFIED: Second.
CHAIRMAN NORQUIST: Second. We have a second. Okay. Any discussion now about this? Yes, Ellen?

MS. SIGAL: I have a question, it’s not about the Letter of Credit, but it’s about the moving costs, the set up costs for the new space. We looked -- you know, because we’re only going to be there, what, four or five years, how long did we take this space for?

MS. YAN: We signed the lease through the end of 2018, it’s a sublet space, so at pretty deep discounts, and we also signed a year and four months of prime lease with the landlord so that we would have the lease co-terminate with the lease we have on L Street.

MS. SIGAL: Great.

MS. YAN: So, we did not plan to sign any lease that would go beyond the current lease period of our office space right now.

MS. SIGAL: Great. And what about the moving costs? Do we have a lot of renovation to
do? Are we taking it as is?

MS. YAN: We are doing some renovation. However, because the rental rate is so low, so we are able to offset that and we are not going beyond what we have in our budget already.

MS. SIGAL: The issue is what you have in the budgets?

MS. YAN: We have factored into our budget additional office space at the current rental rate at our office on L Street.

MS. SIGAL: Thank you.

CHAIRMAN NORQUIST: Thanks, Ellen. Okay, any other discussion? Okay, all those in favor?

[Chorus of ayes.]

CHAIRMAN NORQUIST: Anybody oppose?

[No response.]

CHAIRMAN NORQUIST: Now, what was it you said we had to sign this or something?

MS. YAN: You would have to sign it.

CHAIRMAN NORQUIST: My name? My name?

It's got Steve --
MS. YAN: No, I have another piece of paper, an appendix of this, that I will have you sign. Yeah.

MR. LIPSTEIN: This is Steve.

CHAIRMAN NORQUIST: Yeah. I can hear you, go ahead.

UNIDENTIFIED: [Inaudible.]

CHAIRMAN NORQUIST: You need to add yours too. I didn’t hear the first part of it.

UNIDENTIFIED: [Inaudible.]

MS. YAN: So, we’ll take care of the collection of signatures.

CHAIRMAN NORQUIST: Okay. All right. Thank you. Is that it? Okay, Regina, you want to do the financial?

MS. YAN: I would like to give you a review of our financial. This is a five-month financial. Ideally, we would like to give you a six-month, which is mid-year, but at the time when we prepared the materials in April, the financials available was from February.
I’ll go over some of the key accomplishments for the period, and not repeat what you have heard today in many of the presentations, and then we will go over the revenue, cash balance, funding commitment, and our cumulative obligations as well as a budget versus actual through the period of February.

I will not repeat some of the things that you have heard today, but this year we -- in December you have approved $191 million of projects and you probably wonder when you are going to see the next slate actually a winter cycle, the proposals will be going through merit review actually this week, on Thursday, and we hope to, in July, bring a slate of projects to you for your approval, and also spring cycle applications including the pragmatic trials and others that were issued, and we do have merit review that’s scheduled for August and we hope before the end of fiscal year in September we will be bringing to you the spring cycle projects for your approval. So,
we do have two cycles of award that we plan to bring to you for your approval before the end of the fiscal year.

And also this fiscal year we have on board 38 employees so far and I know that a lot of Board members are concerned about how we will absorb the new employees at this rapid pace, so we do have developed on-boarding programs, we have also now to implement our first annual performance review for our employees.

For our revenue this year as of February, we have received revenue of $206 million, which includes the appropriation of $120 million and also the CMS funds for $86 million and we have a cash balance of $488 million, which includes the funds we have in the trust funds as well as the money we have in the bank.

And for 2014, we have an approved funding commitment of $528 million. You approved $191 in December. At this moment we are projecting to a little over $400 million by the end of this fiscal
year and our plan for 2015 is about $600 million that make up the two years of $1 billion of funding commitment plan.

And cumulatively, since inception, we have awarded $525 million. This includes all our funded contracts including PCORNet contracts awards as well as the coordinating center. And out of the $525 million, we have an obligation of $468 million that represents the payments that we still have to make.

DR. WEISMAN: For clarification, maybe this touches on what Rick asked earlier, but what form of accounting do we do? Do we do cash -- cash basis, accrual basis, management commitment basis? Because some of the judgments on how to view some of these things depends, I guess, on the exact accounting mechanism.

MS. YAN: Okay, let me address that later after --

DR. WEISMAN: Okay.

MS. YAN: -- I finish this.
If we look at our 2014 budget versus actual, 2014 budget is $182 million that you have approved, all of which actually includes about $100 million in research spending. Research spending refers to actually the actual research spending reported back to us by our awardees. And our budget through February, $68 million, and our actual spending is only $26.5 million, and I will go over the variants with you.

Here’s a summary of the budget versus actual in categories, which also represents the broad categories in the approved budgets. So, if you look at this, our approved budget is $182, budget through February $68, spending is $26, and so we have a $42 million of variance, out of which about 70 percent of it is in the research spending, and I will go over later in the detail of what that is and why.

And after that, about 10 percent of that variance is in science, another 10 percent in management in general, about 7 percent in contracts
management.

MR. KUNTZ: Your first column is your fiscal year budget and then the spends are year-to-date?

MS. YAN: Yes. The second one is budget year-to-date through February.

And there are two major causes to the difference between our budget and our actual, one is some cost savings and the other one is delayed expenses. And I’ll go over the details of what the delayed expenses are.

We have several areas of delayed expenses, number one is, as we are projecting our research spending, how much we think that we will receive from our awardees in their reported spending, we developed that forecast using the model that we will have contracts executed within 90 days after the Board approved them, and then 90 days after execution, we expect to see invoices coming in because right now we’re issuing cost reimbursable contracts. So, that was the forecast model that we
used.

But right now we are seeing these invoices coming in pretty slowly, so we are now analyzing some of the patterns to see whether that model needs to be reviewed and then our forecast needs to be adjusted because one thing is sometimes with universities, the majority of our awardees are universities, sometimes the pace is probably slower than we would hope even though we use a very aggressive forecast as our model, because we do really want to see all those expenses coming in.

DR. WEISMAN: Could I please ask you to maybe -- because it looks like you’re using a cash basis of accounting here?

MS. YAN: Yeah, because what we issue, they are contracts, they are not grants, so we can only recognize the expenses as they report back to us. But what we do, as soon as we receive those invoices, we recognize it.

DR. WEISMAN: As I understand, I’m not an accountant, but as I understand it, in order to
make sense of under-spending, because that’s what it looks like, in fact, if we were accruing -- and I think under accrual it’s the services rendered, in other words, they’re actually doing the research but they’re not billing us yet?

MS. YAN: Well, but we don’t know how much.

DR. WEISMAN: So, we don’t have a way of --

MS. YAN: Exactly, so the only way that we know is when they send in the cost proposals or they send in the invoice.

DR. WEISMAN: And then the other -- I mean, typical of government is that they would do a --

MS. YAN: They would do the obligations --

DR. WEISMAN: At the time --

MS. YAN: Of the payables. Right.

DR. WEISMAN: Because it makes it hard as Board to know why we’re so far behind if on an accrual basis or on a --
MS. YAN: Well, there is one thing I know that --

DR. WEISMAN: In that case we would know that actually the money is being spent.

MS. YAN: Yeah, I know that, you know, a lot of times we tend to look at here to see whether research has been done, you know, so what we’re looking at now is that is not the place that is going to give us the answer, and I want to go back to an earlier question about meeting milestones, whether that is a useful metric. For us right now we go back to that one because for us to see -- since we can’t look at the invoices coming in, the measurement of whether the research has been done, so now we are looking into our science staff as we talk to our awardees, as we’re tracking their milestones, and to get assurance that research is actually being done and they are actually making progress.

MR. KUNTZ: I think I’ll press you on this a little as well. It’s really hard to manage if
you’re just looking at the pure cash price and you should have -- we should have a budget outlined for each grant. There should be expected fixed expense, right, that the grants laid out, there’s some variable expenses too, which you might not know until you get your invoices, but we should be able to have some projection accrual of expenses so that we can actually look at whether or not we’re spending correctly.

I think we also should have a metric that looks at outstanding invoices just like you would do DSO and other things like that as well. So, I mean, I just think that it’s a better way for us to manage if we can project what the actual expenses are as opposed to waiting for the mail to show up and see how turns in an invoice, especially for academic institutions, which you already acknowledge, you know, don’t actually keep up to pace.

So, I don’t know how difficult that is to do it, but I mean, my guess is a projected budget
for each of these grants, at least we can track to what’s projected expenses were, right?

DR. WEISMAN: This is sort of arcane, but this would be very unusual for an organization like this to use cash basis accounting. You know, governments usually use the commitment and businesses usually use the accrual method, and only small businesses use what we’re doing because it’s so hard to do it.

MS. YAN: I’m going to have Pam Goodnow.

[Discussion off microphone.]

MS. YAN: Yeah.

MS. GOODNOW: We are using accrual basis accounting so expenses are about one month behind as they would be with anybody. If someone fails to invoice us, we are accruing for them. So, it’s just that there’s a very slow start to the expense and it is a concern.

MR. KUNTZ: Just for a little bit of clarity. If you -- on the previous schedules that you showed, you showed a pretty big gap, so I’m a
little bit concerned about that. If you think that
that’s on track, then we should have an indication
to suggest that that gap is on track, right?

MS. GOODNOW: Yeah, and so, what we’re
finding is that people just are not starting the
research. When we get an invoice, it’s for the
previous month, it’s just that it took some number
of months to get either work together -- a lot of
people have to rent space, hire, so --

MR. KUNTZ: I guess the thing is that the
actions we can take are that if someone’s not
starting the research, then we should take action
on that, because that’s -- we have to compel people
to do research. They’re not turning in their
invoices, we’re not going to compel -- I mean,
that’s not going to be something we can fix. And
the question is, how do we figure out which is
which? And when you had the variances, you had
variances to year-to-date, which I wouldn’t call a
variance, I would call the variances the year-to-
date expenses expected. So, it just seems like if
you’re starting in January you’d have a big variance, right, because you’re looking at fiscal budgets versus the actual spend.

MS. GOODNOW: Actually the way that the budgets are done by the awardees is it’s just, they give us a year, so year one, two, and three, so we didn’t know -- we don’t know what to expect on month one, two, and three. What we do know is when we’re getting our invoices they are for the previous month, so if work is being done, it’s in a contemporary way.

MR. KUNTZ: I just want to make a general statement. We just have to know what levers to pull. And so, if some of the lack of spending is lack of activity, then it’s the Board’s obligation to make sure it gets moving.

MS. GOODNOW: And we’ve been having those discussions -- science to science has been having those discussions on a regular basis, so we meet weekly. We make sure that people understand who’s behind and if there are problems, what they are,
and that they’re being addressed, and that they have a comfort level that we’re moving forward.

CHAIRMAN NORQUIST: So, look, I think that the problem here is it’s not on track. And there is concern and, Kerry, you’ve expressed some concern about the spending too, and so that -- and so, see, we really do need to look at this, and I agree with Rick, I mean, there may be some levers we can pull and some we can’t if people are just delaying and we need to rethink what they’re doing. They may not be able to get into the field for some reason or something and that’s a serious science issue, perhaps, or maybe it’s some other issue.

But it is a concern that that difference in what we would have expected to have spent, regardless of how we account for it, and not being there, I think regardless of how we account for it, we’re behind. Let’s be clear about that, right? Okay.

So, we do need to figure out where those points are about what it is and see what we can do.
I mean, it’s not, obviously, the accountant’s problem. It’s a problem just internally that we need to figure out, right, Kerry? You may want to say something about this since you’re --

MR. BARNETT: Well, we’re going to hear some other instances from Regina here. I mean, I think you put your finger on it. The concern is that we as an organization want to, as much as we can, consistent with our strategic plan and consistent with our goals and objectives, we want to rev up the activity, you know, kind of recognizing that it’s -- as an organization, we’re on potentially a limited timeline and we want to be able to demonstrate to the GAO and Congress and all of our stakeholders the impact of the great work that we’re doing, and that means kind of revving things up.

And, you know, some of the issue that Regina’s presenting to us is, I think, you know, our eyes were bigger than our stomach and we were predicting that we could get more done in general -
- and I’m speaking generally to the issue as
opposed to just to the research piece. We had
hoped and intended to, I think, rev things up more
quickly than we were able to.

Clearly, you know, all the discussions
that we’ve had at the meeting here today shows a
huge amount of very impressive work being done and
if you compare kind of quarter over quarter and
year over year, where we were a year ago, it’s
really very impressive, you know, the significant
advancements that we’ve made.

Still, I think, you know, as the budget
spend shows, we’re substantially behind what we
originally thought we were going to be at. Now,
when I say substantially, as Regina said, it’s
about, what, 60, 61 percent behind where we thought
we were going to be and I think that gives us all
some level of concern. We’ve had some very direct
conversations at the FAC level with Regina, with
Pam, and with Joe and others, and I think they’ve
certainly heard our concerns and are being very
responsive to those concerns.

But ultimately, at the end of the day, this is about making sure that we’re able to accomplish what we set out to accomplish.

One of the variances that Regina, I know, is going to talk about is on the staffing side. If you remember, there were some very ambitious intentions in terms of staffing up for these activities and that staffing has occurred more slowly than anticipated.

If we’re bringing the people on more slowly than we had thought, that means they’re not engaged yet and they’re not doing all the work that we thought.

Some of the variances that you’re going to hear about are due to efficiencies. And hey, that’s great. That’s exactly what we want. Being under budget is always better than being over budget, except when being under budget is because we’re doing less or accomplishing less, and they’ve very much heard our concerns and we’re sort of
revving up our activities, but that’s really the issue that I think is on the table here today.

CHAIRMAN NORQUIST: I’m sorry, just one second, I need you to just kind of sit here for a minute and think about this because we’ve gone into the public session and we need to respect the peoples’ time. We have a person here and then somebody’s on the phone, so if it’s all right, Regina, I’m sorry, but we’ll have a hold here for just a second on this and I’ll give us a chance to have our mathematical minds working here or something.

So, I’m going to ask Sue Sheridan, who is the director of Patient Engagement, to come up to the front or wherever you want to be, and we have one -- I think you told me we have one person here in person who wants to say something and then someone on the phone. And then if we don’t have anyone else, we’ll use the rest of this time for this discussion. If not, we’ll use the next period. Thanks, Pam and Regina, for just a minute,
thank you.

Okay, Sue?

MS. SHERIDAN: Great, thank you, Dr. Norquist. I believe we only have one person on the phone but there may be others that may have called in during the afternoon, but I just want to share kind of our process. You’re familiar with the process, but for those on the phone I want to share this. We’ll take comments from the people here in the audience first and after that we’ll ask the -- our operator -- I understand our operator is Michael. Michael, are you on the phone?

OPERATOR: Actually, [unintelligible].

MS. SHERIDAN: Oh, I’m sorry. Hi. Welcome. And then we’re asking that for those who may be listening but are not going to offer testimony that you can send comments into email info@pcori.org as well. And then all testimony and everything -- all materials submitted to us will go to the Board or the Methodology Committee or staff or whoever’s appropriate for us to consider in the
work that we do.

So, at this time I’d like to introduce
Sarah Van Geertruyden who is with PIPC. Sarah’s
also a member of the Patient Engagement Advisory
Panel that’s been meeting twice a year. So, we’re
going to ask that Sarah keep her comments to three
minutes and then we will open it up to the phone
lines.

MS. VAN GEERTRUYDEN: Great. Thank you.
I’m Sarah Van Geertruyden, executive director of
the Partnership to Improve Patient Care, which you
probably know as PIPC.

Thank you for the opportunity to provide
comments. I want to first thank Sue for her great
leadership. We had, I think, one of the most
productive engagement panel meetings that we’ve
ever had in our last session last week. I thought
it went very well.

I also wanted to thank Jean Slutsky.
We’re excited to be working with her in the future
and hope to have many more round tables. As I’m
sure you’re aware, we’ve been doing a series of roundtables over the last couple of years.

So, my comments today are actually going to be centered around a recent roundtable that PIPC held related to PCORI’s development of an evaluation roundtable, which included members of our steering committee and members of the patient engagement panel to discuss how PCORI can and should be measuring their success.

So, I very much appreciated the participation of Kristen Konopka and Suzanne Schrandt in that meeting.

The summary and recommendations that came from that roundtable are available on the PIPC website. To summarize, the roundtable group identified that PCORI has a dual role being both a mission-oriented, nonprofit, the mission being patient-centered research and it is research funder.

It was the view of the roundtable group that PCORI’s mission should be a core component of
its evaluation framework to support the brand that
PCORI is trying to develop and that brand is
“research done differently”. An important step in
developing this brand is to better define, through
its evaluation metrics, what makes PCORI truly
different from other research organizations,
patient engagement, the use of advisory panels to
prioritize research, and the application of
patient-centered criteria that must be included in
all of PCORI funded research. This will get
PCORI’s brand “research done differently”
credibility.

We also agree that PCORI should be using
best qualitative and quantitative metrics in its
evaluation framework. So, if “research done
differently” is the brand, it is the qualitative
measures that will immediately distinguish PCORI
from other research organizations. Although it’s
vital for PCORI to conduct rigorous research to
ensure it has a high quality product that leads to
an enduring high quality brand, it is the mission
of patient engagement and research that makes PCORI immediately different.

For example, quality measures could identify standing innovations for PCORI’s work, which include things like the use and replication of PCORI’s engagement practices and patient-centered programs.

Our roundtable concluded that the aspect of the evaluation framework focused on PCORI’s patient-centered mission should have a three-year timeline and many of the measures being used would immediately identify PCORI’s commitment to its patient-centered mission.

Although we’re pleased that the draft evaluation framework recognizes the value of patient engagement and usefulness of information, we do hope that the final evaluation framework will capture whether there was adequate patient and stakeholder involvement in topic generation and research prioritization on the broad funding announcement process as compared to the targeted
process that uses advisory panels.

I was interested to hear Dr. Krumholz’s comment about identifying the headline for research at the early stages of developing the research question as a means to determining its usefulness in very practical terms. This is a view very consistent with our roundtable discussions. I would argue that the headline to which he refers is really driven by the patients and providers that will either use or not use the research findings at the point of care.

Therefore, this point underscores even more the importance of engaging patients and providers in determining the usefulness of potential research questions early in the process of topic development and research design. Related to dissemination, it also concerns me that I often encounter patient and provider groups that are not aware of the research PCORI is already funding that targets populations they serve simply because they’re not stakeholder partners in that individual
project.

Although this is a natural consequence of a broad funding announcement process, we hope that the dissemination and implementation action plan provides PCORI with guidance to address this issue.

PIPC has consistently recommended that PCORI engage those groups that will be integral to dissemination of specific projects at the front end of research so that there is an eagerness and demand for the research upon completion. Their engagement in the dissemination strategy will assure that the research is disseminated in a manner that is useful and is therefore more likely to be actually used. This all gets to the should/would/could gap, which you were talking about earlier.

In closing, PIPC is pleased to see the transition to targeted funding announcements and meaningful engagement of advisory panels and we thank you for considering our recommendations and for this opportunity to comment.
CHAIRMAN NORQUIST: Thank you very much.

MS. SHERIDAN: At this time, we can open
the telephone lines. Do we have somebody who would
like to offer some comments?

OPERATOR: [Unintelligible] press the
number 7 on your telephone keypad. Our operator
will ask for your name and organization and place
you in the queue. When it is your turn to speak, I
will announce your name noting that your line is
now open. Please hold while we wait for the first
question.

DR. DOUMA: Sue, while we’re waiting,
could you tell us how many people are on the line?

MS. SHERIDAN: [Inaudible] that I know of.
I believe we have a Ms. Cadwallader?

DR. DOUMA: You’ll scare her away.

CHAIRMAN NORQUIST: I think your question
was the number of people listening, is that
correct? Do you know the total number just
listening? Twenty.

OPERATOR: The first question comes from
Danny Cleary [phonetic]. Please go ahead.

MR. CLEARY: Good afternoon. I just had a question. I am a patient that was on a clinical trial -- I was on the call earlier today and I heard the gentleman talk about reducing costs by collaborating. One of my questions is, I suffer with Hepatitis C and I have cirrhosis of the liver, and I was on the clinical trial in 2010. Fortunately, the staff guided me through the process, but as an African-American, what I wanted to know, will PCORI be having trials that will look at the different things that impact people who are taking medications on clinical trials for Hepatitis C?

DR. SELBY: Well, this is Joe Selby. You might have noticed in the presentation this morning under the listing of pragmatic clinical studies, one of the high priority topics that was invited to go forward was in fact a comparative effectiveness study of newer treatments for Hepatitis C, so that has not been funded, but we’re expecting an
application.

I agree with you, it’s a very important area with a lot of questions both about effectiveness and the tremendous costs because of the very, very large number of people in the population who are infected with Hepatitis C. So, I agree with you completely. It’s a very good topic for comparative effectiveness research. There’s a lot we need to know about the relative benefits and possible harms and the effectiveness of different treatments.

OPERATOR: If you have a question, please press the number Q or the number 7 on your telephone keypad.

[Discussion Off microphone.]

DR. SELBY: -- range of outcomes that are important to patients, so I think certainly -- first of all, you said recovery and so I think recovery is pretty much aligned with ability to function again. So, functional status is a very important outcome and I think in most conditions
we’re going to expect to see something other than simply the number of readmissions, although in some conditions, and with appropriate patient engagement, I think we could be convinced that having to go back to the hospital and be readmitted again and go through that whole routine is a real concern to patients.

So, I think readmissions is an interesting one because it sounds a lot like it’s a health system worrying about costs, but it’s also, I think, a patient and a patient’s family worrying about really having to go through this again.

So, I would say that readmissions has some real interest of patients, but you usually see it – in a PCORI study you usually see it coupled with reports on how patients are functioning. You probably wouldn’t see it alone in a PCORI-funded study.

MS. SHERIDAN: Thanks, Joe. Operator, do we have any other people on the line who would like to submit a comment?
OPERATOR: We do not.

MS. SHERIDAN: Okay, thank you very much. If there’s anybody else that’s listening, you can submit it electronically and we will respond to that.

Does the panel have any -- the Board have any other questions?

[No response.]

CHAIRMAN NORQUIST: Okay, thanks, Sue. And thanks to everyone. So, we’ll go back to our discussion that we were having before and we’ll lead off with Bob Zwolak. You had the last --

DR. ZWOLAK: Bob Zwolak, Board. My only comment was I think in this biggest category that Regina is describing as behind budget, it’s not PCORI or PCORI staff that’s behind, it’s the scientists that we’re funding who are behind on their spending. Isn’t that correct?

MS. YAN: That is correct. We are doing two things here, number one is we’re evaluating our original model to see whether it’s too aggressive
and not realistic based on the pace that they’re sending us the invoice. Secondly, most importantly, is to monitor the milestones and make sure that the project itself is progressing, meeting the satisfaction of our fine staff.

CHAIRMAN NORQUIST: But I would say that – I mean, Kerry, some of the discussions I thought we had had, part of the issue has also been not enough program officers sometimes to do some of the work too. I mean, I think it’s the staffing also. So, on some, I mean, I think it’s both sides. I mean, yes, the scientists are not getting in, but I think it’s also the amount of effort that we’re able to do to help them, you know, with some of the project staff and stuff.

So, hopefully as we hire more people, have them in, this will move ahead quicker too.

MS. YAN: Maybe one thing we can do more is really follow up with our awardees as we are not seeing the costs coming in.

Another factor we talked earlier about is
the hiring. We set a very aggressive goal for ourselves to fill -- to have 142 head count by the end of second quarter. But we were at about 115 at the end of February. But I do want to give you the latest data because the head counting is every day -- a new employee arriving every day. As of today, we have 122 employees. We have six employees that are waiting to start. They’re not on payroll yet, they’re scheduled to start, and we have five offers ready to be made, so we are looking at 133.

So, what that means is that in the seven months since the beginning of the fiscal year, we have recruited and filled about 56 positions.

We have five months ago, until the end of fiscal year to meet our 165 target. That means that in the next five months we have about 32 more positions to fill.

In the last seven months we have filled about 56.

And obviously, we are not filling the positions as quickly as we can, we have under
spending in personnel and other related expenses.

We have several areas that we have real cost savings. We did a lot of workgroup meetings and landscape reviews for the targeted PFAs that we developed in previous years, so as a result, we include all the funds in our budget for this year. For that, you know, if we need it we have it, but the thing is, as we decide to have the pragmatic trial PFAs going out, and that does not require workgroup meetings or landscape reviews, so as a result of that, the funds that we have budgeted for PFA development we did not need to utilize it.

In addition, because we do have a few more staff this year than last year, you know, our staff have also done some of the work that previously was done by contractors.

In addition, in contract management, which runs the merit review process, we also have included some efficiencies and we have some cost savings there. Now we are using a standing panel with the reviewers. We also have some of our PFAs

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use competitive LOIs so that also changed the cost
element for us with our streamlined contract
template, that’s been improved. We also have
reduced cost and timing.

I think as we move forward we will
continue to have some cost efficiency there.

MR. KUNTZ: So, if we’re starting to make
the conclusion that this very ambitious process
here might have been a little bit too ambitious but
everybody’s moving the right direction and you’re
staffing up and some of these sites are potentially
trying to get coordinated, we want the good science
to be committed and we want it to be completed. Do
we need to alter our expectations of a three-year
project to go to four years? Should we start
thinking about that?

Because I think these are $500,000 a year
for three years plus the projects, and if we’re
recognizing that actually there are some things
that we didn’t account for, but we’re seeing really
good activity, but it’s a little delayed, should we
start to actually change the structure of those
grants so they will be completed?

MS. YAN: I think that’s a science
question.

MS. GOERTZ: Yeah, Christine Goertz. I
just want to echo Rick’s concerns that the odds
that all of our projects are going to end, you
know, right on time within the amount of time that
we actually had originally anticipated just doesn’t
exist. I’m trying to think if I’ve ever finished a
randomized clinical trial on time, quite frankly,
and my guess is the answer is no. And it’s just a
very complex process.

It takes longer than you can ever imagine
that it’s going to and because there were some --
particularly when you’re starting a new program
like this, I think, and bringing in new
stakeholders and a different type of investigative
team, I think it’s realistic to imagine that it’s
going to take longer and that as we’re looking at --
-- you know, I’m not quite sure what criteria to use
for trying to decide whether people are on target with their goals or deadlines, but I think we need to be thinking about is there data that we can capture early on that will actually help us get a more realistic estimate of when we’re actually going to be spending money, because my guess is that the funding -- that will be more common than not that the funding gets pushed into some sort of a no-cost extension.

CHAIRMAN NORQUIST: Yeah, so, one of the key indicators is recruitment of subjects. I mean having done this for many years and then we got into this issue when I was at NIH to start requiring at a certain endpoint if you didn’t have this percentage of subjects, then we were going to cut it. I mean, basically, at some point you know somebody’s not probably going to be able to recruit the number of subjects and you have to deal with that or you have to keep pouring money into it to keep it going.

So, that’s an early indicator, but I’ve
never in all the 15 years I did all these, I never
saw maybe one or two trials finish on time. I
mean, and they were pretty small trials too. And
we’re doing some larger trials with some
complicated settings and stuff, but non -- I mean,
when you’re in the real world it takes even more
time.

MR. KUNTZ: [Unintelligible] accounting
structure, if we do see legitimate reasons why
they’re a little bit slow for the uptake, and
again, we want to get good research, do we have a
request -- a requirement that they spend the money
at the end of each fiscal year? Is there a method
for us to carry dollars over? This is something I
think we --

CHAIRMAN NORQUIST: So, do we, Regina? I
mean, that’s a good question. This is Gray.

MS. YAN: Well, one thing is we are new
and we are under significant pressure to show
results. So, we have not spent a lot of time
thinking about how we let people have more time and
delay it. So, we’re focusing more energy on how we
get people -- get their work done as quickly as
they can.

CHAIRMAN NORQUIST: No, I know. But the
problem is that if we commit money and we get up
front where we tell a bunch of people that we’re
going to give them -- I’m just making this up now --
$10 million and only $5 of that is spent and then
we’re putting more, we better keep up with the $10
we already committed and we may have to push that
down the line or something as they get into it.

And we should have a plan at some point to
say, you know, you’re a year and a half behind,
you’ve only spent ten bucks. I think it’s time to
call it quits. We’re not going to keep letting it
go. I mean, I’m exaggerating, but I ran into these
very situations and we got -- it got very
difficult. And you had to just say, you know, it’s
not worth it now. We’ve put some investment in,
but we’re not going forward. We’ll put it into
something else.
MS. YAN: We definitely need to add that -

CHAIRMAN NORQUIST: Well, this is something we have to have a conversation -- we're not going to solve it here, but we do need to have this conversation and come up with a plan.

UNIDENTIFIED: We need to have a carry over and no cost --

CHAIRMAN NORQUIST: Absolutely, we need to have a policy on that. Yes, Harlan Weisman?

DR. WEISMAN: Yeah, Harlan Weisman.

Couple points. One, in terms of, Kerry, what you were saying, you spoke very knowledgably about what’s accounting for the variance. Putting aside the discussion on how do we account for things, what would be very helpful for me as a Board member is to understand the sources of variance with a little more detail.

For example, how much of the $27 million or approximately first quarter gap is due to slowness of a program? How much of it is due to
slowness of an invoice? How much of it is due to improved efficiencies, which as you said, it’s a good thing, because I don’t know how much worry I should have, although it sounds like from what you were saying, a lot of it may be slowness to launch.

The other thing is, just in terms of running a research enterprise, at least in the private sector, which I have a lot of experience on, I would agree that this is not uncommon for research organizations to over budget and under deliver, and in fact, they’ll do it perennially. But on any given -- and I’m not saying that’s a good thing, on any given project, the expectation should be that you’re delivering when you say you’re going to deliver and you measure it’s performance.

But from a budgeting the enterprise standpoint, I don’t know what the right numbers are for this one, is I went to managing what I called a probablized likelihood, and I basically took everybody, what they said they were going to do,
and then budgeted 70 percent of it. I held everybody accountable to deliver, but I knew at least 30 percent wasn’t going to be on time and that kept -- because it’s bad for an organization to over budget as much as it is to under budget, because that money could be used for other things and I think we need to make sure that, at least in high priority areas, we may have to do tighter management of our sites. All research, particularly clinical trials, have inertia. It’s very hard to get them going. On the other hand, I know that if you focus attention when you’re managing them, managing investigators, you can get them going. You’ve got to figure out what their particular issues are and pound the pavement, so to speak.

So, these are all levers that we have.

CHAIRMAN NORQUIST: Yeah. Kerry, and then Debra.

MR. BARNETT: Kerry Barnett. If I could just respond. First of all, it’d be great to set a
time with both Pam and Regina, with you, Harlan, to
go over some of those details in the specific
budget variance reports. There’s a lot of data
there and so it can be spelled out with great
granularity.

You know, our focus right now in this
discussion is talking about the budget, and I guess
what I would really stress is that I think the real
issue for the Board is not focusing on budget under
spend or over spend, but to go back to the last
presentation about the score card, because I think
what our focus should really be on is, what are the
goals of the organization, what are the activities
that we’ve laid out and committed to, and how are
we tracking along those commitments, that that’s
really what we should be focusing on. It’s far
more important than kind of what the specific
budget variance report may be telling us.

At the end of the day --

DR. WEISMAN: But that’s fundamental to
our Board, is looking at the finances.
MR. BARNETT: But I guess that’s really what I’m saying is that if there’s an issue on the table here -- I don’t think there’s anything wrong with the finances, I’m very confident of that. If there’s an issue, it’s around the pacing of the organization, which is exactly what Joe is addressing when he lays out the scorecard. Should we be doing different things? Should we be going faster? Should we -- are we accomplishing what we set out to accomplish?

I would just say that that, I think, is what the real focus of the Board should be on.

CHAIRMAN NORQUIST: It's Debra's turn unless you want to just follow up on this particular --

DR. SELBY: Okay, I’ll be really quick. And I think that sometimes looking at the finances can give you a window into what’s going on in the organization, so at least just these kind of questions. I’m sitting here furiously emailing people behind me to try to figure out why I told
you -- why I told you that -- I’m so lazy. This is Joe Selby, by the way -- I just reported to you that 67 percent of the projects were on target, right, meeting their milestones at one and two quarters, and then Pam’s explanation for why we’re under spending is that they haven’t gotten started on their work.

And so the dashboard forced me to try to ask that question that I might not have otherwise asked. So, that’s it.

CHAIRMAN NORQUIST: Debra Barksdale.

MS. BARKSDALE: I'm changing the subject. This is Debra Barksdale and this is an easy one. You’ve talked about staff growing and needing to grow even more, and I know previously there were a few contract employees and I think on the previous slide you said that had been reduced. What is the current number of contract employees?

MS. YAN: Well, as we are staffing up, we still have some -- there’s some work done by contractor because they are not meant to be there
for a long time. So, we keep those. We have some contract staff on site. We have probably about a dozen of them right now and some of them will be rolled off as the staff comes on board.

I want to talk about --

CHAIRMAN NORQUIST: I think -- no, we have another question up here, and I think the big question is, have we reduced the percentage of contractors -- I mean, because that was always the question that we had and how much have we reduced that and brought more in-house, right?

MS. YAN: Well, we had about 20-some contractors just supporting contracts management last year and right now, you know, we probably have half a dozen. So, that has significantly reduced.

CHAIRMAN NORQUIST: Okay. Allan, you have a question?

DR. DOUMA: This is sort of, I guess, a little bit of a change. I’m not sure whether you’re done or not, but just -- one of the variables that is easy for outside people to track
and therefore important for us to track as well is what percentage of our budget is spent on research and is that -- we added some numbers, you know, a year ago. Are we tracking that on an annual and/or quarterly basis? And what do they look like?

MS. YAN: Yes, we are tracking them. In the approved budget, our administrative rate was at 16.5 percent and then as of February, you just look at the February actuals, our administrative rate was at 25 percent, that’s year-to-date.

DR. DOUMA: The administrative rate is a funny term. It depends on what you want to put in administration. That’s why it’s, I think, more useful to have what percentage of your budget is research and are you saying that that’s 84 percent or is it a -- is it in the research? The numbers that show this --

CHAIRMAN NORQUIST: That would be 75 percent.

MR. BARNETT: Are you saying research or program? Because obviously program is a broader
Dr. Douma: Right, I was saying research in particular.

Chairman Norquist: Remember, we also have engagement. I don’t know how engagement gets --

Dr. Douma: And I think engagement can be thrown into research because of who we are, but if you combine research and engagement, what percentage --

Ms. Yan: Are you talking about just the awards or are you talking about the programmatic works?

Dr. Douma: What I’m talking about is what anybody on the outside will think goes into research so we can communicate.

Dr. Weisman: We made a commitment, or you made a commitment to us, that our administrative fees were high as a percent of total budget because of our size, but that as our spending increased, our administrative versus operating would go down. In fact, it’s going the other way.
MS. YAN: Well, the spending depends on when the spending comes in.

CHAIRMAN NORQUIST: Yeah, part of the problem is, she’s giving you a percentage of -- we got the problem the research dollars run out, so the percentage that’s administrative, but what we have now is going to be high. What is it in the budget, basically, is the question?

MR. KUNTZ: The question is, do we have an operating statement? I mean, that’s generally what the Board should see, and the operating statement will lay out what the operating overhead is, what the programmatic costs are. It would be just answered by one schedule.

CHAIRMAN NORQUIST: So while they’re looking at that I think Alicia has a question.

DR. FERNANDEZ: I actually had a comment more than a question.

CHAIRMAN NORQUIST: Okay.

DR. FERNANDEZ: I hope it’s helpful. As you know, I’m newly on the Board and I’m even more
newly on the administrative committee. I believe they wanted someone who would play the role of the Village Idiot and say, oh, how --

CHAIRMAN NORQUIST: Come on, Alicia, you’re not the Village Idiot.

DR. FERNANDEZ: After all, I’m a physician and almost by definition a poor administrator. But this is a relevant introduction because I don’t want to feel, even though I’ve only been to one meeting or two meetings, that the administrative committee has failed the staff in anticipating what the Board would want. And I wonder whether instead of pursuing sort of ad hoc questions, we could take a little bit of time to reflect either -- perhaps not in this session, perhaps in another session -- to reflect on how one would want -- what would be the right dashboard that the Board would like to see on the financials? What are the right metrics? What would the rest of the Board like? Is it the -- do we always want to know the current administrative to expenditure section or whatever
the right metric is?

And then, if we had that from the rest of the Board, then perhaps as an administrative committee we could do our job better of backing up the staff to make sure that when they present, they have -- they’re presenting what we want and are in a full position to be able to answer the question.

Anyway, just a thought, and feel free to always come to me because there is no question that is too silly for me to ask in that committee.

CHAIRMAN NORQUIST: So, Alicia, you have proven that you’re not the Village Idiot. So, and she has a good sense of humor, which -- and actually this committee is meeting tomorrow morning, early, for West Coast people. I just don’t understand why you torture yourself that way.

So, but I agree, I think that’s one of the issues that the FAC is supposed to be responsible as the Board committee to do this, and I think we could give them some input. And I think you’ve heard a fair amount and I think -- about some of
the concern about the way the information is
presented so that it does make some sense.

I think what you’re also hearing is just
concern that we’re behind in our spending. We do
not want to have a public image of our
administrative fee being too high if it’s not. I
mean, if it really is not in the budget or the
commitments or whatever, you know, it’s not. If it
is, then we need to address why it is high and is
that where we want it to be and what is high. I
mean, if it’s 50 percent, it’s obviously high.

Okay, Regina, what else did you guys want
to do at this point?

MS. YAN: I just want to quickly go over
the next steps that we plan to do. Right now, we
will be doing a reforecast of our spending for this
year, looking at the actual spending so far and
also looking at the latest cost assumption and our
program timelines, so we do plan to come back to
you and present to you our reforecast for this
fiscal year sometime in June.
CHAIRMAN NORQUIST: And this would be done in conjunction, obviously, with Alicia, Kerry, and the rest of the folks on the FAC, right, so that we will, as a Board, know that this is the kind of input --

MS. YAN: Actually, all the presentation reviews have been reviewed with the FAC.

CHAIRMAN NORQUIST: Okay, so the input for our questions, we will make sure that we get to the group. Okay? All right, thanks. Other questions? Comments? Allen, did we get you? Are you still -- okay. I think that’s it, right? Everybody’s enough now?

MS. YAN: So, if you have any further comments about our plan to reforecast, you’re welcome to send me your comments. Thanks.

CHAIRMAN NORQUIST: Thank you. So, that’s the wrap-up, I think, and I can’t -- I have to put my glasses on. I can’t read the closing comments here. So, I want to thank everyone who was on the call. All of the information that you saw today,
the slides and the recording of this Board meeting will be on our website at PCORI.org and we always welcome feedback at info@PCORI.org.

So, Joe, any final comments you want to make? I’ll let you.

DR. SELBY: Well, I thought this meeting today was really good in helping us both think through the evaluation and just suggestions. I’ll just mention these briefly in case I’ve got something wrong or in case I’ve overlooked critical points.

I don’t have --

CHAIRMAN NORQUIST: We have tomorrow morning also.

DR. SELBY: Just for our public audience. So, one of the encouragements I heard from the Board, and this was new to me, was this notion that we should not only be proactive about this issue of privacy, but we should really be conveners in this world. This is really our role, to convene the sides, if you will, in this discussion about
weighing the benefits, the great potential of big data type research, with the serious, legitimate concerns about privacy and data security, that in the area of clinical trials PCORI may be able to play a role in pushing the price point for trials down. This is linked to PCORNet, but also to our pragmatic clinical studies initiative, and even consider, and I think this really can go back to the SOC for some serious discussion, consider the idea, when we clearly know the research question that we need contracting directly with a PI or seeing a PI with a good idea and contracting with them to do the research, perhaps even in another population or other infrastructure; that we need to get a version of our standard operating procedures that’s suitable for public -- for the public, into the public eye; that we need to get our methods checklist and other materials as quickly as possible into the public so people can use them, so people can use them for teaching and be familiar with PCORI’s -- with the methods, standards, and
the tools to teach them; that we have some work to
do in presenting our expenses -- Rick and Harlan
both had some good ideas there that I think we need
to follow up on in the line of projecting expenses
for individual contracts, trying not to be
completely handcuffed, if you will, by being
limited to what funds have actually gone out the
door, but also investigating further this issue of
outlyng and slow invoices.

I still want to get further into the
question of whether the delayed invoices reflect
delayed billing or delayed research activities. I
think it’s not an answered question yet.

Several suggestions for the dashboard,
that we should definitely have a separate item on
the number of PCORI-funded publications separate
from those studies -- those that are written by
PCORI or about PCORI; that we need to have a clear
understanding of -- explanation of what it means to
be -- for projects to be up to date and meeting
their milestones or not meeting them. We really
need to flesh that out with some background information. And then a metric that we can, again, probably work out with Harlan, Rick, and the FAC on what metric on the dashboard gives us a look, over time, at the proportion of our expenditures that are going for research versus administration.

Did I miss -- I bet I missed a few important topics, I usually do.

CHAIRMAN NORQUIST: We can talk about it more, but I think that’s good.

DR. SELBY: I thought Dr. Levine had her hand raised.

DR. LEVINE: Just a clarification. I don’t think it was research versus administration, it was administrative expenses versus programs research and the content related work of PCORI.

CHAIRMAN NORQUIST: Yeah, it’s administrative expenses overall versus the content stuff that we do.

DR. LEVINE: Right.

DR. SELBY: And it was noted that
engagement should be combined -- programmatic
expenses for research and engagement should be
combined with the external expenditures supporting
research and contrasted with the administrative
expenses.

DR. LEVINE: Right. Right.
CHAIRMAN NORQUIST: Correct. Okay.
Alicia? That was from earlier. Thanks, everybody,
and then we have -- Debra, are you having your
publications committee or something?

MS. BARKSDALE: Yes. The scientific
publications committee is meeting now in the
Potomac Room.

CHAIRMAN NORQUIST: Well, 5:30 is what --
5:30 to 6:30, I think, and then there’s a dinner at
7:00 and then we will reconvene tomorrow at 9:00
for our closed session and you guys have your FAC
early.

[Whereupon, at 5:17 p.m., the PCORI Board
of Governors meeting was concluded.]