PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

Tuesday, September 20, 2022

Washington, D.C.

[Transcribed from the PCORI webinar.]

B&B REPORTERS
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APPEARANCES

BOARD OF GOVERNORS PRESENT:

KARA AYERS, PHD
JENNIFER DEVOE, MD, MPHIL, MCR, DPHIL, FAAFP
ALICIA FERNANDEZ, MD
CHRISTINE GOERTZ, DC, PHD [CHAIRPERSON]
MICHAEL HERNDON, DO
RUSSELL M. HOWERTON, MD, FACS
JAMES HUFFMAN, MSC
SHARON LEVINE, MD [VICE CHAIRPERSON]
BARBARA J. MCNEIL, MD, PHD
EBONI PRICE-HAYWOOD, MD, MPH, FACP
JAMES SCHUSTER, MD, MBA
KATHLEEN TROEGER, MPH
ROBERT OTTO VALDEZ, PHD, MHSA
DANNY VAN LEEUWEN, MPH, RN
ROBERT ZWOLAK, MD, PHD
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Kathleen Troeger, MPH, Chair,
Work Group to Optimize Effective Governance and Board Engagement

Christine Goertz, DC, PhD, Vice Chair,
Work Group to Optimize Effective Governance and Board Engagement

Nakela L. Cook, MD, MPH

VOTE

Recess

Consider for Approval:

Recommended Strategies to Leverage PCORnet® to Advance PCORI’s National Priorities for Health and Evaluate PCORnet Performance from the PCORnet Priorities Stage Two Workgroup

Robert Zwolak, MD, PhD, Chair,
PCORnet Priorities Work Group

Kara Ayers, PhD, Vice Chair,
PCORnet Priorities Work Group

Erin Holve, PhD, MPH, MPP, Chief Research Infrastructure Officer

Laura Forsythe, PhD, MPH Director,
Evaluation and Analysis

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PROCEEDINGS

[9:02 a.m. EST]

MS. THOMPSON: Dr. Goertz, the floor is yours.

CHAIRPERSON GOERTZ: Thank you so much, Maureen. Good morning and welcome to the September 20, 2022 meeting of the PCORI Board of Governors. I'm Christine Goertz, Chairperson. Welcome to everyone who’s joined us for today's Board meeting. We're pleased to have you.

Maureen, would you please call roll?


DR. AYERS: Present.

MS. THOMPSON: Kate Berry.

[No response.]

MS. THOMPSON: Jennifer DeVoe.

DR. DEVOE: Present.

MS. THOMPSON: Alicia Fernandez.

DR. FERNANDEZ: Present.

MS. THOMPSON: Christopher Friese.

[No response.]
MS. THOMPSON: Christine Goertz.

CHAIRPERSON GOERTZ: Present.

MS. THOMPSON: Mike Herndon.

DR. HERNDON: Present.

MS. THOMPSON: Russell Howerton.

[No response.]

MS. THOMPSON: James Huffman.

MR. HUFFMAN: Present.

MS. THOMPSON: Connie Hwang.

DR. HWANG: Present.

MS. THOMPSON: Sharon Levine.

DR. LEVINE: Present.

MS. THOMPSON: Barbara McNeil.

DR. McNEIL: Present.

MS. THOMPSON: Eboni Price-Haywood.

[No response.]

MS. THOMPSON: James Schuster.

DR. SCHUSTER: Present.

MS. THOMPSON: Ellen Sigal.

[No response.]

MS. THOMPSON: Larry Tabak, Director of the NIH, or Michael Lauer, designee for the NIH
Director.

[No response.]

MS. THOMPSON: Kathleen Troeger.

MS. TROEGER: Present.

MS. THOMPSON: Robert Valdez, Director of AHRQ.

DR. VALDEZ: Present.

MS. THOMPSON: Daniel van Leeuwen.

MR. VAN LEEUWEN: Present.

MS. THOMPSON: Janet Woodcock.

[No response.]

MS. THOMPSON: Robert Zwolak.

DR. ZWOLAK: Present.

CHAIRPERSON GOERTZ: Thank you, Maureen. As a reminder to everyone, Board members' conflict of interest disclosures are available to the public on PCORI’s website. These disclosures are required to be updated annually and when the information changes.

As a reminder, if the Board will deliberate or act on a matter that presents a conflict of interest for you, please recuse yourself or inform

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me if you have any questions. If you have questions about disclosures or recusals relating to you or others, contact your staff representative.

Today's meeting is being recorded. Members of the public who have logged onto the webinar will see that the slides that have been prepared for the Board meeting. The agenda for today's meeting, along with the approved minutes from the Board's prior meeting, and an archived webinar will be posted on PCORI's website within a week.

Board members participating on-site who wish to speak should turn their tent card up. Board members participating remotely should indicate they wish to speak by raising their hand.

All right. I'd like to -- could we have the next slide, please?

We have a somewhat of an action-packed agenda today. We will start out with our approval of the minutes from our prior meeting and as well as committee nominations relating to Board transitions that will be followed by the Executive Director's report, and then we will consider for approval our
2023 budget, a proposed governance framework; as well as proposed strategies to leverage PCORnet, to advance PCORI's National Priorities for Health and to evaluate PCORnet's performance. We will then conclude with a farewell for outgoing Board members and then we will wrap-up and adjourn the meeting.

We do not have any public comments today.

Board members, please remember to keep us informed -- I think we can see you who are here in the room, whether if you leave, but if you are joining us virtually, please let us know if you are going to be leaving the meeting because we have a number of voice votes and want to make sure we're keeping track of attendance.

All right. Could I have the next slide?

So our first order of business then is to approve the minutes from our July 26, 2022 Board of Governor's meeting. Can I please have a motion to approve?

DR. VALDEZ: So moved.

DR. McNEIL: So moved.

CHAIRPERSON GOERTZ: All right. We’ll go
with Bob Valdez. I heard him first. And then, Barbara, are you okay with seconding that motion?

DR. McNEIL: Of course.

CHAIRPERSON GOERTZ: Thank you so much.

All right. Any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All those in favor of approval, please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[No response.]

CHAIRPERSON GOERTZ: Abstentions?

[No response.]

CHAIRPERSON GOERTZ: Okay, thank you.

I would now like to invite Sharon Levine, our Chair of the Governance Committee, to introduce the next agenda item related to board transitions.

DR. LEVINE: Thanks so much, Christine.

With the upcoming transition in Board membership, the Governance Committee has the responsibility of ensuring that the current Board-related committees are able to fulfill the
governance requirements in their charters in the period between the departure of current Board members, which occurs Midnight Thursday night this week, and the appointment of new Board members who are then able to be oriented and named to serve on committees.

In order to meet these governance requirements, the Governance Committee is nominating several of our current Board members to support the function of these committees and so that the committees remain in legal compliance. Each of these Board members has previously expressed an interest in serving on these committees, and the Governance Committee is very grateful to each of them for being willing to serve in these roles.

Can I get the next slide, please?

There are two motions today for you to approve. The Governance Committee is recommending that the Board approve two motions, one to appoint additional members and leadership to the specified committees as reflected on this slide. To the

Finance and Administration Committee: James Huffman
as Vice Chair of the committee, Kate Berry as a member of the committee, and James Schuster as a member of the committee. And for the EDIC, Engagement, Dissemination, and Implementation Committee, appointing Connie Hwang, Vice Chair of the Committee.

The second motion -- actually, why don't we take a vote on this? Can we do that?

CHAIRPERSON GOERTZ: All right.

I'd like to ask for a --

UNIDENTIFIED SPEAKER: [Off microphone.]

CHAIRPERSON GOERTZ: Okay.

DR. LEVINE: All right.

CHAIRPERSON GOERTZ: Let’s do them together.

DR. LEVINE: We'll do them together.

The second -- next slide please.

The second motion for the Board. The Board resolves that if the Chair of a Board-related committee resigns or is no longer able or available to fulfill the responsibilities of the Chair position, the Vice Chair of the committee is
appointed to the position of Chair of the committee unless otherwise appointed by the Board.

And this is so that there is no question about succession, should there be a need for someone to stand in for the Chair of the committee. This does not, of course, require the Vice Chair serve in that role, but it does create a path for succession and to prevent a gap in leadership in the committee.

CHAIRPERSON GOERTZ: Great. Thank you, Sharon.

DR. ZWOLAK: A point of clarification. On the previous slide, with the appointment of three new members to the Finance and Administration Committee, will Russell Howerton still remain Chair? And does that mean there will now be a total of four Board members on the committee? Because previously, I believe, it was only three.

DR. LEVINE: Yes, that’s correct. And that small number at times created an issue in terms of quorum. And so, this is an effort to add members to the committee.

DR. ZWOLAK: Excellent. As an outgoing
number of the FAC, I strongly support the addition of an extra member. Thank you.

DR. LEVINE: Okay. Can I get a motion to approve both of these motions.

DR. HERNDON: Mike, so second.

DR. McNEIL: Second, Barbara.

DR. LEVINE: Thanks Barbara. Thanks, Mike.

CHAIRPERSON GOERTZ: All right. Is there any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All those in favor of these two motions, please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[No response.]

CHAIRPERSON GOERTZ: Abstentions?

[No response.]

CHAIRPERSON GOERTZ: All right, thank you. And thank you to all of you who have agreed to serve in this capacity. I know I speak on behalf of the Governance Committee and the entire board with that appreciation.
All right. Next, I would like to invite our Executive Director, Nakela, to give her report.

DR. COOK: Thank you. Good morning, everyone. It's wonderful to see you here and on the line. I have a few things that I just wanted to update you on in my Executive Director's report today. I wanted to introduce another new member of the PCORI leadership team. Also give you an update on some of the ad hoc working groups and committees relating to the Board and where they currently are in their trajectory of focus. And then, give you a few highlights as we start to close out the fiscal year of 2022 in terms of looking at the year before.

Why don't we go ahead to our next slide.

So my first order of business is really to welcome Mieka Martinez as our inaugural Chief Financial Officer at PCORI. Mieka's joining us from Howard University and has been on the job for a few months now. And at Howard, she served as the Vice President and Interim Chief Financial Officer, as well, as Assistant Vice President and Deputy
Financial Officer. And prior to that, was at Georgetown University, where she held several different roles including strategic, operational, and financial roles there, and was the Director and Chief -- Director and Chief levels at Georgetown.

We have just been thrilled to welcome Mieka. She's really a seasoned Executive with 38 years of experience related to strategic financial management and operational leadership and will be overseeing at PCORI, our finance and administration, including procurement activities. And so, we are excited that she has that in her background and was able to bring that experience to us.

And as you can see here, she did all of her training at Georgetown University and both her Master of Business Administration and her Bachelor of Science degree in Business Administration.

So what a joy to welcome her and to round out our leadership team with Mieka Martinez.

We can go ahead to our next slide.

I also just wanted to give you a few updates related to the ad hoc committees and work
groups relating to the Board. And this slide should look a little familiar to you, in terms of the way in which we tried to chart the ongoing work and demonstrates the most active work groups and committees at a glance. Just to provide you a quick update. So you can see here the charge and composition and timeline of the work, as well as some of the outcomes to-date.

And the first order of business here is to thank all of you who've been serving on these work groups and committees. They have been really important opportunities for us to pull together products in a very short period of time for the Board to consider.

The reason that I have first on the left, the Strategic Planning Committee, is because the Strategic Planning Committee wrapped up its work in July of this year. And so, I wanted to make sure that the Board had that report that it has completed the task. And as you know, they began working back in August of 2020 on pulling together the strategic plan for the organization and working on behalf of
the Board to do that, and delivered the plan in June when it was approved by the Board of Governors.

You can see at the next column there, the PCORnet Priority Stage Two Working Group. And you'll hear more about this work later on in the Board meeting today. This work actually began with the Stage 1 group that identified the prioritizing principles for Phase 3 funding for PCORnet. And their work was conducted between November of 2020 and January 2021. And then, the Stage Two group, whose report you're going to hear today, has really built upon those strategic prioritizing principles from the Stage 1 group and has pulled together strategies to help inform the evaluation of the PCORnet, as well as to guide the Board's consideration for future investments, as well as to strategies that will facilitate advancing the strategic plan and how the PCORnet can play a role in really advancing the National Priorities for Health and Research Agenda.

So this group will recommend their strategies to you today, and their work will then be
concluded as we move on to start to implement -- if those strategies are approved by the Board.

In our third column here, you can see the Work Group to Optimize Effective Governance and Board Engagement. And this working group was formed to develop some options for an evolved approach for the Board's strategic oversight of PCORI's work. And you can see here that it also is wrapping up its work and presenting to the Board today a proposed governance framework with a new Strategy Committee that you will be considering shortly.

One of the things that I just wanted to mention here, is that there were several desired outcomes of the work here underway. And one was really to evolve the Board's approach and being grounded in the Board's governance vision and priorities and culture statement. And another was to make sure the Board had the opportunity to be flexible in meeting the changing organizational directions and the needs of our evolving external environment, and to maintain our focus at a conceptual and strategic level in order to provide
strategy and policy direction, and to make sure that we had effective structures and mechanisms for committees and work groups that report to the Board and overall alignment with the Board's fiduciary duties and legal requirements. So we'll be excited to present that to you a little bit later.

And the last column here, I'm going to spend a little bit more time on, and that's the Healthcare Cost and Value Work Group, whose work is still ongoing -- as you can see here. You heard a report from the Healthcare Cost and Value Work Group back in February of this year. And you may recall their charge was to develop a framework for the activities to support PCORI's approach to collecting the full range of outcomes and informing the value conversation and supporting some policy priorities.

And the membership here has been across the Board of Governors, the Methodology Committee members that are participating on this work group, as well as staff leadership. And this group has anticipated to continue its work through December of this year, but thus far has produced a framework to...
approach activities, a landscape review that I'll highlight on the next slide, and several stakeholder listening sessions.

So let's go ahead to the next slide.

So here I wanted to just mention that when we spoke with you back in February, at that time we indicated that over the summer we would be pursuing two activities to help us and our applicants, as well as our stakeholders, better understand the conversation around value and health and healthcare, and particularly patient-centered value. And these activities are centered on patients and focused on informing the value conversation. And on September 2nd, we published on the PCORI website a landscape review of patient and stakeholder perspectives on value in health and healthcare. And this piece really synthesizes and summarizes the perspectives of posted publicly across many stakeholders that are interested in PCORI's work, including patients.

And we identified four initial domains and 48 broad components of value that are included in this report, and it's going to serve as a foundation
for further engagements of patients and stakeholders as we move forward. And so, we kind of adopted an approach that snowballed in terms of building our growing and understanding in this space. And we've listened to and learned from our stakeholders about healthcare cost and value from a patient-centered perspective.

And it's culminated in a multistakeholder workshop that was hosted on September 7th. And we were very excited in this workshop to bring together nearly four dozen patients and stakeholder community representatives who participated. And the goal was really to help identify which components of a definition of patient-centered value and healthcare are critical to which stakeholders and why, and how we can consider measuring that.

So we believe we're really learning and synthesizing all of this and we'll have another forthcoming report that will be of value to PCORI, and to all you, our applicants, stakeholders, and patients coming the stakeholder workshop. We can go ahead to our next slide.
I also just wanted to transition here and just give you a couple of highlights from this past fiscal year and the spirit of the year in review. And we've been doing this for a few years now, just to kind of think about how we're progressing against some of the goals we put forward for the year.

We can go the next slide.

So one of the big goals for the year has been to recruit and onboard to fill out our leadership team at PCORI. And we are pleased that over the course of the late last fiscal year and this one, that we onboarded seven new leaders at PCORI, you can see them all here. They've been introduced to the Board at varying stages during the year, and we're just excited to bring all of their talents to bear on PCORI's work and bring a compliment of talented staff into PCORI to those that are already here as well. And we're starting to really build that leadership team and the family at PCORI that's ready to execute on all aspects of our work.

We can go ahead to the next slide.
Another major accomplishment of this year is where you're all sitting today, in PCORI's new offices, and we couldn't be more excited to move into this consolidated space and for the staff to be able to come together to build that kind of collaboration and community that's necessary in order to support PCORI's work. For the teams here at PCORI, their grand opening will be next week and we're pleased to have our first Board meeting in this space.

As you can see that the space also offers that type of convening opportunity for us to bring our stakeholders together here in the organization.

We can go to the next slide.

As I mentioned earlier, one of the, I think, biggest accomplishments of the year really relates to PCORI’s Strategic Plan and all of the work of all of you in helping to pull this plan together which was approved at the June Board meeting. And it really does provide that roadmap for the years ahead. And the plan builds on a lot of our past work, which is really a nice way to
reinforce and promote the use of CER evidence into the future. It also recognizes that need to remain responsive to an ever-changing landscape of healthcare, as well as to approach some of the biggest challenges facing the nation.

What I think was really key to this plan is the extensive stakeholder input that was received in order to shape the plan and formulate the plan, and point out some very important things of particular importance for PCORI to think about and emphasize in our work, including that broadening and diversification of the communities that lead and participate in the research that we fund, as well as how we can leverage the research we fund to advance a path towards health equity, generating a lot of that evidence that'll help to improve care and outcomes for patients and others who have been traditionally underserved by the healthcare system.

We can go to the next slide.

I also really think that one of the great achievements was the core of this plan, the five National Priorities for Health that were identified
as those ambitious long-term goals for PCORI. And these are all generated from that extensive stakeholder input and feedback. And together they really work to reinforce each other as well as create interconnections across PCORI’s activities and promote both this kind of broad and deep partnerships that we think are going to be necessary to make progress on the plan.

As well as, I think, if we're really going to address some of the biggest challenges in the nation, that it's going to require us thinking about how we work across these priorities for patient-centered health.

We can go the next slide.

And another, I think, major achievement of the plan was the articulation of the fact that there's a holistic approach to generating and promoting the use of evidence that really builds upon the patient-centered CER that we fund, but also the importance of the dissemination and implementation of that work, leveraging infrastructure investments as well as the importance
of engagement that works throughout all of these domains.

So our core parts of this work really work together, synergistically, to drive toward the achievement of those National Priorities for Health. And the Board really, I think, hit it out of the park in thinking about how these things work together to enable the types of things we want to see for PCORI's future work.

Let's go to the next slide.

One other accomplishment I just wanted to highlight this year was a major advancement around thinking about the role of the Methodology Committee to advance a vision for its future, aligned with the work in strategic directions that PCORI was pursuing and conceiving of the Strategic Plan for the several years to come. And the vision was presented at the Board meeting in March of this year. And that work actually resulted in several items that the Board approved to set up some of the necessary steps to implement that vision, including amending the Methodology Committee charter, as well as revising
the conflict-of-interest statement or policy in
order to incorporate Methodology Committee members
more fully into PCORI's activities, and an improved
framework for nominating and appointing new
Methodology Committee members.

And excitedly, we actually recently closed
our solicitation for nominations to fill seats on
the Methodology Committee and had a really robust
response from the community and the Board will
consider those appointments for nomination at a
future meeting.

We can go to the next slide.

So this past year, we also had an award
winning PCORI Annual Report. We are delighted that
the annual report was awarded a MarCom Award. And
this is the third consecutive year that PCORI's been
recognized for the Annual Report. And the MarCom
Award program is really one of these international
creative competitions that recognizes outstanding
achievements by marketing and communication
professionals. So it means a lot that we're seeing
that kind of recognition of the work at PCORI, in
addition to what's entailed in the report, in terms of the content and the progress that has been made.

We can go ahead to the next slide.

Last year we had our second Virtual Annual Meeting, and now we're approaching our third. But during the fiscal year, last year, was the second one. And you know, what was exciting about this is we had over 3,700 registrants and over 2,100 attendees, and the content remained online and people continued to access that content. But as we're gearing up for our Third Annual Meeting, we are already seeing our registration outpacing where we were at this time last year. So that's going to be really exciting to see forthcoming in October.

We can go to the next slide.

This year we also launched PCORI's new website. Hopefully you've had a chance to kind of peruse the website and take a look at it, but it has an updated look and feel to it. And it's undergone more than just a cosmetic makeover. It really does allow for the groundwork to introduce new features and content, expanded information on our portfolio.
with tools and filters that allow people to identify the work that PCORI's funding, as well as fresh layouts for funding opportunity announcements so that people can find the announcement pages and a news hub for PCORI.

There's also this kind of one-stop learning resource about what's happening at PCORI, such as the registration for the upcoming Annual Meeting. As you can see featured here by one of our keynote speakers this year, Kirsten Bibbins-Domingo.

And the website was really designed to kind of showcase PCORI's work as a source of information, but also demonstrate the impact of our work, engage diverse stakeholders, and really modernize the vehicle that we have to highlight our work for the experience of different visitors that come to our site.

We can go to our next slide.

And I'll spend just a little bit of time here because one of the things that we were able to achieve last year was really the advancement of several new innovative initiatives that we launched
at PCORI. And all of these really build on the strengths that we have and that holistic approach I mentioned in terms of engagement, dissemination and implementation, comparative effectiveness research, as well as iterative learning and partnership building as we really strive to move forward with our National Priorities for Health.

And the first one you see mentioned here is the Health Systems Implementation Initiative. Many of you may recall this is a new initiative that was launched in February to broaden our efforts to move findings from PCORI-funded work into practice by really leveraging the ability of health systems to lead implementation efforts within their healthcare delivery settings.

And so, the goals here were to leverage the health system's commitments to providing evidence-based care and engage the experience and expertise that many of these organizations have with implementing practice change and prepare for the future scale-up of evidence-based practices by demonstrating some successful approaches that work
for a diverse array of health systems.

You may recall that there were kind of three steps to this initiative. And the first stage was to select the health systems that were going to be participants in the initiative. And this is the exciting part where we are right now, we've had applications come in here and we were very pleased with the response. We received applications from health systems from every region of the country. And they range from smaller systems to those that serve more than 200,000 patients to large health systems that serve millions. And we also see that many of the health systems that applied are serving underserved communities, one of the goals of this initiatives.

So the merit review is underway and we'll be announcing participants in February of 2023.

The second step though, is that they then are eligible for the funding opportunities for capacity building funds to help the systems prepare for the conduct of their implementation projects. And in that third stage, then they will be able to
then apply for the funding opportunities for the specific implementation projects that are of interest to them. So really an exciting time with that.

The next initiative here that was quite different and innovative for us was the Health Equity Initiative, where we're framing up a new approach to thinking about CER studies that we're calling Partnering Research and Community Organizations for Novel Health Equity Research or the Partner Initiative. And it aligns squarely with our National Priority for Health around achieve health equity. And this is one that's focused on a multicomponent and multilevel type of intervention approach that will simultaneously address health conditions as well as the social determinants of health in order to improve maternal health outcomes, which is one of our priority focus areas for research at PCORI.

So we're really excited that there are a couple novel features in this one, which is the requirement of community organizations to be full
partners with the research organizations from the application all the way through to the conduct of the work and the dissemination and implementation, and leveraging partnerships that already exist between communities and researchers and research institutions.

And another feature is that we’ll have flexibilities in terms of the number of rewards that -- I mean number of projects that an awardee can take on in order to really meet the needs identified by the communities.

The third one you see here is around Science of Engagement, which many of you remember is a bit novel for us in some ways because it's about building on some of the efforts that we've already learned in the past decade or so about what works in engagement and what doesn't work in engagement. And while we've learned a great deal, we recognized there was still a gap for some of the rigorous evidence to help our understanding of what's most effective in the conduct of engagement. And so, this idea is to help us with understanding through
mechanisms and activities and the strengthening and supporting of the infrastructure within PCORI and the broader research community, what really works with the science of engagement.

We're trying to generate some actionable evidence here that'll help us with thinking about even how we continue to improve our efforts around engagement in the future.

Our Learning Health Systems Initiative is a partnership with AHRQ and was launched this year as well and builds on the first stage of the Learning Health Systems work. And this one was in the first stage was really to support the training of researchers to conduct patient-centered outcomes research in Learning Health Systems.

And in the second iteration, it really is building on that to strengthen some embedded research projects for those that are participating in the program, as well as strengthen some partnerships with health systems and think about flexibilities of scholars at different stages in their career. And it's been a strong partnership
with AHRQ in advancing priorities that synergistic
between AHRQ, PCORI, and HHS. So we're really
excited, too. There's an underlying emphasis across
everything within the Learning Health Systems
Initiative to address inequities healthcare as well.

And the Board will remember that earlier
this year, you approved a set of eight broad
research themes, topic themes, to move forward with
-- or converging with alignment with the National
Priorities for Health and also represent high burden
and high impact conditions and issues for patients
and caregivers and others in healthcare systems.
And these were all resonant with many stakeholders
through the strategic planning process. So we were
really excited to be able to move forward quickly on
what we heard from strategic planning and to
organize these themes to continue the momentum on
the Research Project Agenda that systems from the
Strategic Plan.

These eight themes we think are going to be
critical to allow us to remain nimble, continue our
funding in areas of importance to those that
surround PCORI, and allow for the potential studies that will develop evidence to continue to inform decision-making.

And the last thing I wanted to mention is over this past year we released 11 targeted PFAs, which was really our goal to try to release two or three per cycle in order to think about our commitment plan for the next year. Remember, what we release this year actually will be funded next year and would be part of the commitment plan for the following year.

So we had eight traditional targeted research PFAs. We had two of those innovative ones that you see above the Health Systems Implementation Initiative and the Science of Engagement. The Learning Health System one was released by AHRQ, so it's not included in that 11, but I did want to highlight that one today, and we will look forward to the release of the Health Equity Initiative one soon.

We also had a special Targeted Engagement Awards PFA that targeted smaller or community
organizations. And so, that's included there. And so this is a really exciting kind of announcement to make in terms of the progress and moving and ramping up the number of PFAs that we're releasing.

Can we go the next slide?

And I wanted to round out my report this morning just to let you know about where we are in terms of thinking about our progress on the Commitment Plan of Fiscal Year 2022, a substantial component, really of fulfilling our mission, relates to this Commitment Plan and you may recall when the Board discussed different scenarios and approaches. And that you reached the conclusion that we would have this early upfront funding stage with a ramp up of targets that would be very ambitious in the early years. And the fiscal year 2022 target was $600 million in total commitments and would be up to $650 million if you include that New Initiatives line.

And at midyear, we reported to the Board that we projected closing out closer to $450 million this year, recognizing that our Cycle 3 was our biggest cycle and we were anticipating funds coming
And so, what you see here is that we're actually estimating ending the year somewhere between about 475, to a little over $500 million in awards. And there's a range here just because it reflects the fact that there's some ongoing work to the projects that may still be closing out or coming in toward the end of the funding cycle. And so, if those awards are not made until fiscal year 2023, then it may roll over into the next fiscal year's Commitment Plan.

But here you can also see the estimates by each of the funding lines within the Commitment Plan. And so, I just wanted to take them one by one and talk about them for a moment.

The target for research in the Commitment Plan for fiscal year 2022 is $500 million. And you can see here that our commitments in this award category for this year will come somewhere between about $400 to $425 million there. And while we had 11 PFAs that I talked about for fiscal year 2022, what we're really looking at are the awards that are
coming in from the funding announcements that were
the prior year, in 2021.

And so, you know, some of these did produce
very significant funding, and some of them we
recognized still had more opportunity to fulfill
their intent and goal. And so we set up an
opportunity where we would re-release those as we
wanted to fulfill the full intent of those PFAs and
some of those re-releases cross fiscal years. And
so, that we’ll have to figure out when we talk about
the Commitment Plan in more detail later in December
how we may want to count for that in some of our
modeling.

You can see here, the D&I target was $40
million this year in our Commitment Plan, and we
anticipate somewhere between $50 and $20 million in
commitments there.

And I mentioned to you the Health Systems
Implementation Initiative and other activities,
where the commitments for some of those will really
show up in a future years’ commitment plan. And so,
we do anticipate with some of the things we've been
working on there that we're expecting to see an increase in Dissemination and Implementation awards over future years.

And you can see here for Infrastructure which includes our Engagement awards, PCORnet Infrastructure Workforce, that the target in the plan was $60 million this year and we achieved about $38 million. And of note, there's a $25 million commitment on the New Initiatives line, which relates to the Learning Health Systems Initiative. And so, as a Workforce Initiative, it will be realigned to infrastructure when we close out the fiscal year. And so, that'll bring that line a little closer to target.

I wanted to show you one more slide on the Commitment Plan, if we can go to the next slide. And this slide just tries to put into context this year's commitments related to prior years. And as you can see, prior to this planning activity for commitments, our average annual commitment was about $388 million. And we've been ramping up and in ramp up mode really since 2020.

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with $313 million in commitments that year. And in 2021, about 494. And then you see the range that we're estimating for 2022, and we're about close to where we were in 2021. I think when we land at the end of 2022.

Next year's target is also $600 million in the Commitment Plan, and we're scheduled to have a deeper discussion in December at our Board meeting, to talk about any anticipated needs for adjustment in that plan, revisiting our model, and talking a little bit about what we've learned from the past years that may help us with thinking about projections moving forward.

Okay, let's go to our next slide.

I'm just going to transition a little bit to mention that one of the other things that has been really exciting about this past fiscal year is really just the number of research results that are coming to fruition and garnering attention.

And here you can see some of the highlights of six PCORI-funded CER results publications from this fiscal year that really achieved high levels of
attention is measured by Altmetric scores greater than 300. On the left, you can see those scores. And these are considered pretty high scoring. You can see a couple of things that we've highlighted before, including a study that compared spinal anesthesia with general anesthesia for hip surgery, as well as one that looked at comparative effectiveness of reliever-triggered inhaler glucocorticoid in Black and LatinX adults with asthma.

And there’s also one in here related to the COVID Watch Study, which was around text messaging for monitoring COVID-19 at home and related to our COVID-19 funding. And further down, there's a rapid review on video teleconferencing, which is something that has received a lot of attention related to understanding when and how we use teleconferencing in this kind of telemedicine delivered era.

We can go to the next slide.

So there's just a couple that I thought you may also want to hear about. And the first one here relates to studies that were conducted utilizing
PCORnet, even though funded by others. And the first one had an outstanding Altmetric score, and you can look at that attention score of almost 4,000 demonstrating substantial attention.

And this was published in the MMWR and funded by the CDC leveraging PCORnet. And you can see the focus here was around cardiac complications after SARS-CoV-2 infection and mRNA COVID-19 vaccination, and this was one that I think garnered a lot of attention in terms of understanding some of the effects such as myocarditis and others that follow vaccination or COVID-19 infection.

There's a second one on this slide that also used PCORnet, but was externally funded, and this one was funded by the NIH as part of the Recover Initiative, which is focused on the sequelae, the post-acute sequelae of SARS-CoV-2. And here this one was a retrospective study that use some data from nine different hospitals, children's hospitals in the PCORnet network and of children that were tested for COVID-19. And it basically found that there was a low burden of pediatric post-
acute sequelae of COVID-19 and presentation to health systems. And that myocarditis was actually the most commonly diagnosed post-acute sequelae associated condition in children and that some of the kind of drivers for that related to acute illness severity in young age and comorbid chronic disease.

And so, this was I think another very significant utilization of PCORnet, funded by the NIH and collaboration in terms of thinking about the important questions of the day.

And then there's one other one that I highlighted on this slide, which is on the left. It's called the BP Check Study. And this was one that was funded by PCORI, but was a three-arm randomized trial of adults with elevated blood pressure and compared three different ways of monitoring blood pressure; whether in the clinic, at home, or at the kiosk versus the 24-hour ambulatory monitoring for effectiveness of and diagnosing hypertension.

And it basically found that monitoring
blood pressure at home had better diagnostic performance, adherence, and acceptability than either the clinic or the kiosk for diagnosis of blood pressure. So another important finding of PCORI’s work that I think can actually move us forward in terms of thinking about clinical care.

You can go to the next slide.

So the last slide here is just really to talk about briefly, and we'll come back to this later, one of the major milestones that we're marking this fiscal year, and it's a bittersweet one. It's the celebration of 12 years of service for four of our founding Board members, Christine Goertz, Sharon Levine, Ellen Sigal, and Robert Zwolak. And their efforts really formed the foundation for many of PCORI’s successes over the past 12 years, and really all of the highlights we just talked about of this last year. And so we look forward to a very special sendoff for them a little later today to honor their dedication to PCORI. And I look forward to talking more about them at that point in time, but I couldn't end my Director's
report without acknowledging this.

So thanks, Christine, for time this morning.

CHAIRPERSON GOERTZ: Thank you so much Nakela. All right. I'd like to open up the floor for questions or discussion.

All right. Mike. We'll start out with Mike Herndon.

DR. HERNDON: Nakela what do you see, you know, as PCORI’s role in staying current with the, you know, like just monkeypox and polio resurgence and what -- does PCORI have a role in trying to stay nimble and responsive? You know, and how do we collaborate our efforts with the other public health collaborators and things like that?

So could you just kind of explain your perspective on how we address these emerging concerns?

DR. COOK: I think that's a fantastic question. And one of the things that we do very regularly as our way of staying in touch with where the landscape is, is staying in touch with the
stakeholders. And so, stakeholders include other agencies, federal agencies, as well as patients and others in the healthcare community. And so we are regularly engaged in understanding where the priorities are, what people are seeing on the horizon, and understanding that more fully and being able to capture that input to bring it to the Board for a discussion of potential future activities.

The other point I may mention is that in addition to staying connected to the stakeholders, we also want to stay connected to organizations that are really focused on some of the issues on the frontline, some of the professional organizations and things of that nature, that really raised to our forefront, you know, the issues that are facing clinicians and patients and others.

And lastly, I may mention that one of the efforts of really remaining nimble is the opportunities that we want to think about as we talked about the research themes in terms of bringing things to the Board where we have that opportunity to discuss more fully together the types
of things that even you may be seeing on the horizon that may be important for us to consider as an organization. And because of your connectivity to different stakeholder organizations and groups, I think that's a critical input to that process.

So those are some of the things that we certainly can do. And we learned during the pandemic, the COVID-19 pandemic, how quickly we can pivot certain of our mechanisms, the approaches we have, to target things that may be on the horizon. And it's one of the things I love about our Strategic Plan, is that while we have a plan in place, we wanted to make sure we were nimble and flexible for things that emerge. And so, that's really built in terms of thinking about the way in which we assess the landscape routinely and think about what the next opportunities are.

CHAIRPERSON GOERTZ: All right. I have Bob Z and then Danny.

DR. ZWOLAK: Thank you for that report, Nakela. I'll ask a variation of my standard question. Which is, your thoughts about our
assignment of less than half of the dissemination and implementation proposed award roster and how that came to be and how going forward we can improve on our efforts in dissemination and implementation.

DR. COOK: Maybe I'll mention just a couple of things. One is that there's a component of our dissemination and implementation activities that really resides on the results that are coming to fruition from prior funding.

And so, we are working on with those results in order to think about those that are ripe and ready for some of the dissemination and implementation projects. And that has a bit of variability in terms of when those results come forward for us to be prepared to move them to the next stage of dissemination and implementation. And it's somewhat dependent upon when those come forward.

So part of the excitement of what we saw in the last year, in terms of results coming to fruition, would be those opportunities to move those things forward, but it ebbs and flows in terms of
the timelines. And so, having a static goal and a commitment plan doesn't necessarily always reflect those ebbs and flows and maybe something that we would want to think about when we look at a multiyear plan.

And then the other thing that I briefly mentioned that maybe I'll expound upon just a little bit is that some of the activities that we're gearing up for actually have a multiphase approach that crosses fiscal years. And we really didn't think about that in that way when we were designing the plan. And so, building partnerships, for example, with the health systems. An extremely robust response to that where we think we may have the opportunity to fund that even more than we had initially anticipated. But that's in a stage two or three down the line from the work that we do to set up the PFA and awards.

And so, I think we may also have some thinking to do around timing in terms of how we align the timing of our activities with what we want to see in the deliverables of the Commitment Plan.
So those are some of the things that we thought we may want to talk about when we come back in December because I think we have a better sense now of kind of the timelines of what it takes for certain things to come to fruition and can model that in more effectively.

DR. ZWOLAK: Thank you. As a brief follow up question, do we at PCORI think that our dissemination and implementation effort should be limited to results of studies funded by PCORI?

DR. COOK: We certainly focused there with the concept that a lot of the dissemination and implementation activities around the broader aspects, we work through collaborations with other organizations such as AHRQ, et cetera. And so, there are ways that we extend our work in terms of the partnerships and collaborations that we have beyond PCORI-funded activities, but that's where our funding portfolio really emphasizes.

CHAIRPERSON GOERTZ: All right, Danny, and then I'm going to check to see if anyone online wants to make a comment or has a question before we
MR. VAN LEEUWEN: I'm wondering about the scope we have in our definition of workforce, and does workforce include all healthcare personnel? Does it include non-healthcare personnel? Does it include family caregivers and family caregivers that are also employed?

Like what do we, when we talk about workforce, what's our scope?

DR. COOK: A very broad scope. When we talk about workforce, we talk about all the components that it takes to move forward patient-centered outcomes research, which are all of those that you mentioned in addition to many others.

And perhaps one of the things you may be getting at, is that we do have to think about how we tailor activities to different components of that workforce. And some of that work comes through capacity building activities that are done through engagement awards. Some of it comes through partnerships that we have with AHRQ around the training of investigators or researchers that may be
sitting within health systems. Some of it may come from the thinking of how we embed kind of a training pathway even in current awards or how we think about the opportunities to link up kind of existing awardees with those that may be thinking forward. And there's a component within the health equity initiative, I mentioned, that has that kind of focus.

There are also workforce activities that happen within our infrastructure program related to PCORnet and thinking about the clinical research networks that really have that PCOR focus around them and all those components around workforce that are necessary to make that happen.

So it's a broad, broad definition and our activities span many of those spaces.

CHAIRPERSON GOERTZ: Well, thank you. Is there anyone online that has a question or comment?

DR. McNEIL: Not me. I thought it was a great presentation as usual.

CHAIRPERSON GOERTZ: Well, thank you, Barbara. I appreciate that. And I completely
concur on that. It was an excellent presentation.

James.

DR. SCHUSTER: Yeah, thank you. It was a great presentation. Always really helpful.

I just wanted to follow up actually on Bob's comment around dissemination and just wanted ask if maybe we could think about some additional discussion in a future meeting, or in a smaller committee or planning group or what have you, about potential dissemination strategies that might go beyond our funding of investigators who are requesting funding specifically for dissemination and what additional strategies PCORI might be able to drive around dissemination.

DR. COOK: Certainly. I may have even mentioned that we also have dissemination awards through the Engagement Award program, which kind of takes things a little bit further, too, and an opportunity to move that forward and some of that work gets mapped into our Engagement Awards line of infrastructure.

And we also have a lot of dissemination
activities that go through our stakeholder convenings and one-on-one efforts. So we may want to think about that broad scope.

And I wanted to mention, as well, that one of the areas that we have established in terms of a kind of collaborative effort and activity for planning how our strategic plan and AHRQ’s strategic plan that moves forward, is thinking about things in a collaborative and synergistic way, relates to Dissemination and Implementation.

And so, there's some outputs from that work that we had hoped at some point from that work group's effort, we'd have a chance to report back to the Board. And so that may stimulate some fodder for future discussion as well.

DR. SCHUSTER: Yeah, I was just struck by the, you know, important findings of a number of studies and whether we as PCORI might want to identify some studies that we think are important to disseminate, that we drive some of that work ourselves --

DR. COOK: Yep.
DR. SCHUSTER: -- even if the investigator doesn't necessarily want to pursue that track.

DR. COOK: Absolutely. That's a great point. And we do some of that already, quite a bit of that already, in terms of when we're reviewing findings internally at PCORI, coming out of our peer-review process, identifying the ones that are right and starting to work on how we actually help the investigator team, which often means thinking about other investigators that are more focused in implementation and dissemination work to pick up that work and help move it forward. And so, we start to tee that up as a place that's important. And we also publish that kind of results findings that are primed for dissemination and implementation in order to open it up for the community.

So we'd love to hear if there are other ideas about doing that, but there's a lot we do to kind of push that along.

DR. SCHUSTER: Good. Thanks.

CHAIRPERSON GOERTZ: All right. I'm not seeing any other requests to speak.
And once again, Nakela, thank you so much for that excellent report. I always get excited at the end of the fiscal year to the Executive Director's report. Over the year it's so easy to get caught up in the details of what we're working on, and especially over this past year that there's really been such an intense focus on so many different work streams. And so, it's a lot of fun to see it all pulled together in this, you know, really compelling way.

And also, I want to invite everyone who has not yet had an opportunity to read our 2021 PCORI Annual Report, because I had that same reaction to that. It really is an opportunity to see how PCORI has focused over the last year or so in a way, that for me, is incredibly exciting to see.

DR. COOK: Thank you.

CHAIRPERSON GOERTZ: Thank you. And thank you and thank you to all of -- certainly all the members of the Board, but all the incredible amount of work that this -- that is represented in this report on part of you and your entire staff, is
really something that needs to be noted. So thank you.

And for those who are not here, please convey on behalf of the Board, our thanks for everyone's commitment to PCORI and their hard work over the last fiscal year.

DR. COOK: Thank you. I'm sure they would love to hear that.

CHAIRPERSON GOERTZ: All right, we're going to move on then to the next item. Oh, I'm sorry. I did not see you, Bob V.

DR. VALDEZ: Thanks very much. I also just wanted to express my thanks to the PCORI staff who, particularly those who've been working with us at AHRQ, in a very collaborative way to find those synergistic opportunities particularly in the Dissemination and Implementation area.

As you know, our agency's focused on Dissemination and Implementation brought across a wide variety of findings and researchers and funding sources.

And we, particularly because we're a sister
trust fund agency that is specifically focused on training and dissemination and implementation, those are the pieces that we've been asked to focus on using trust fund dollars.

It's extraordinarily exciting to be working collaboratively with PCORI and to see our joint work beginning to come to fruition.

CHAIRPERSON GOERTZ: Thank you, Bob. All right. We are going to turn then to the next item on the agenda where we will hear a presentation, and then consider for approval the proposed budget for our 2023 fiscal year. And unfortunately, Russ Howerton is our FAC Committee Chair, is not able to join us, so I'm going to ask the Vice Chair, Bob Zwolak, to start with some opening remarks before we turn it over to our Deputy Executive Director for Operations, Brian Trent.

DR. ZWOLAK: Thank you Christine. We all miss Russ. I think he's in the air somewhere. So safe travels to Russ.

In support of PCORI’s mission, the FAC recommends for the Board's approval the FY 2023
proposed budget. This proposed budget represents a culmination of the work completed by PCORI’s departments to outline the key activities PCORI will be embarking on in fiscal year 2023 in support of PCORI's institutional goals and objectives, as well as the cost associated with these activities.

The FAC has had the opportunity to review the proposed FY '23 budget several times now during the last few months, and we recommend it to the Board for approval. I'll now ask Brian to walk us through the budget presentation. Brian.

MR. TRENT: Thank you so much, Bob. Next slide please. Thank you.

So before getting into the budget, first I want to talk about -- I first want to focus on the fiscal year '23 projected fund balance. The fund balance represents the available resources to PCORI, taking all assets and liabilities into account. The key takeaway here is PCORI has sufficient financial resources to cover our outstanding award obligations and any unobligated cash on hand will be available for new award commitments and operating costs to
support the management of PCORI’s programs.

So on this slide, you’ll see that at the beginning of fiscal year ’23, we estimate the fund balance of nearly $1.7 billion. Also in fiscal year ‘23, we expect to receive $607 million in revenue via the PCOR Trust Fund, and we are anticipating a budget of about $451 million, which I will describe later on in the presentation.

By the end of fiscal year ’23, we project a fund balance of about $1.8 billion. Of this amount, we estimate about $1.6 billion in outstanding award obligations. These outstanding award obligations are essentially the amount of contracts awarded for which payment has not yet been made. These amounts will become due and available as research and other projects progress over time, so they may not occur right away in the during this fiscal year.

So please note that outstanding award obligations include assumptions about what we will commit in fiscal year ‘23, so there may be some fluctuations.

And finally, the difference between the

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projected fund balance at the end of fiscal year ‘23 and outstanding award obligations provides a net funds available of about $194 million at the end of fiscal year ‘23.

It should be noted that any unobligated cash on hand will be available for new award commitments and operating costs to support the management of PCORI’s programs beyond fiscal year ‘23.

If we can move to the next slide, please.

Thank you.

The FY ‘23 proposed budget represents a culmination of the work completed by PCORI’s departments to outline the key activities we will be embarking on in fiscal year ‘23 in support of our institutional goals and objectives, as well as the cost associated with these activities.

As we start reviewing the proposed budget, I want to make a distinction between commitments and expenses. The key thing to keep in mind is that the proposed PCORI annual budget that I’m about to go over reflects expenses, not commitments, commitments...
refer to the amounts of funding that PCORI intends to award or has awarded. Once a commitment has been made and a contract has been executed, we will start making award payments to research and other awardees in response to invoices. Additionally, expenses associated with award payments almost always lag behind commitments and are spread over multiple years as research studies and other projects progress over time.

In December of this year, we will begin reviewing the Commitment Plan with the FAC and the Board of Governors.

Now I want to focus on the fiscal year '23 budget.

We're proposing a fiscal year '23 budget of $451 million, which is about $66 million or a 17 percent increase over the $385 million projected expenses for fiscal year '22. The proposed fiscal year '23 budget reflects estimated expenses planned for fiscal year '23, and are predominantly driven by award payments to our awardees in the following key areas: Research, Infrastructure, and Dissemination.
and Implementation.

While the overall proposal for fiscal year ‘23 is expected to increase the proportion of cost for all major budget components is expected to remain approximately the same. Award payments will make up the largest portion of the proposed fiscal year ‘23 budget, and represent approximately 78 percent of all budgeted expenses in fiscal year ‘23.

Program and program support, which provides scientific support and review of award and monitoring of research projects, as well as development of award contracts make up about 14 percent of total estimated expenses for fiscal year ‘23. The $8.7 billion, or 16 percent, in these programmatic expenses will provide PCORI with additional resources to support new initiatives that are driven by the recently adopted Research Themes and the National Priorities for Health, which were adopted in October of last year.

Lastly, administrative support makes up the remaining eight percent of the total budget. The small increase of four percent in administrative
support will allow us to enhance PCORI’s cybersecurity and data privacy, as well as to provide additional resources related to operational functions.

And with that, I will turn it back over to you, Christine, for any discussions and to review the motion.

CHAIRPERSON GOERTZ: Thank you. Thank you so much, Brian, I appreciate it.

I understand that Russ may have been able to join us.

Russ, are you on the line? If so, would you like to make any comments?

DR. HOWERTON: No, Bob did an excellent job. Thank you very much.

CHAIRPERSON GOERTZ: Thank you. And safe travels. All right, I'm going to open it up for discussion. James.

DR. SCHUSTER: I just had a question, and I'm pretty sure I know what the answer is, but I just wanted to confirm it.

Are we required to have the funds on hand
before we make the commitment, even though the
commitment's over many years and we know that
there's going to be an ongoing funding stream in
those future years?

MR. TRENT: In terms of having the entire--

DR. SCHUSTER: Yes. I was asking because
it was kind of implied by the presentation, right?
That we had so much money and funds made these
commitments.

MR. TRENT: Yes. That's right. The funds
will be on hand before we make the commitments, yes.

DR. SCHUSTER: Okay, thanks.

DR. COOK: Can I make a comment?

MR. TRENT: Sure.

DR. COOK: I'll just add one thing, James
though, is that we're not required to have it on
hand to make the commitments because we have a
mandated appropriation. But when we went through
the Commitment Plan with the Board, there was an
approach that the Board wanted to take in terms of
making sure that we didn't get too far ahead of what
was anticipated.

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And so, we'll be talking about that more when we come back for the December Commitment Plan discussion.

DR. SCHUSTER: Okay.

DR. COOK: But our plans right now incorporate that idea that we are within what's coming forward and anticipate they would be on hand before committing, but we follow a philosophy the Board would set that policy and direction on.

DR. SCHUSTER: So we could re-look at that at some point.

DR. COOK: Mm-hmm.

DR. SCHUSTER: Okay. Thank you.

CHAIRPERSON GOERTZ: All right. Thank you, James. I've got -- actually I see Barbara's hand up and then Bob and then Mike. Okay. Alicia, too.

DR. McNEIL: Should I ask a question now, Christine?

CHAIRPERSON GOERTZ: Yes, please Barbara.

DR. McNEIL: I have one question that I think the Board members know, but this is a public meeting and it's probably not immediately apparent
what the extra $10 million in infrastructure costs covers. So maybe you could say a word about that.

DR. COOK: I'd be happy to, Barbara.

So the infrastructure cost are part of the award payments, which means that it's related to what we've already committed and when we anticipate those commitments coming forward for payments against those awards, and infrastructure includes things such as our Engagement Awards, our PCORnet, and funding, as well as things like Workforce Initiatives.

And so, we can see a little bump in that related to what we're committing, and we know we've committed some additional funds for the Learning Health Systems. We know that we've increased some of the work with the Engagement Awards, and then we'll have that multiyear plan for paying out the expenses against the PCORnet.

And so, those estimates line up year-by-year in that line. So hopefully that helps a little bit in explaining that.

DR. McNEIL: Thanks.
CHAIRPERSON GOERTZ: All right. I have Alicia, then Bob, then Mike.

DR. FERNANDEZ: Hi, I have two questions and a small one, and maybe a little bit of a larger one. And thank you, Brian, for that very clear presentation.

I don't know who my question should properly be addressed to.

So the smaller question has to do with actually in inflation. And I am curious whether or not the program officers and others are hearing back from researchers that they are finding it hard to meet their projected expenses or how increased costs and increased salaries are affecting the research, if at all. If we're hearing anything about that.

And then my second question has to do, it's sort of a larger question, and it has to do with the amount left over or uncommitted in fiscal year -- at the end of fiscal year '23. And I don't have a handle on whether or not we consider that too large, too small, or just right, and what the Board's roles or opportunities may be related to that.
So thank you.

MR. TREN T: So are you referencing the $194 million that we are anticipating having at the end of the fiscal year?

I mean, I think that that is -- it's an approximation, but I think it's just right because I think that can, you know, there's some fluctuations, it could be a little bit more, a little bit higher, but I think we can also use those funds to add additional awards. So I think that is the appropriate amount.

DR. COOK: I was going to add a point that we talked about with the FAC, which is that in the way that we set forward the Commitment Plan, the goal was to kind of, and this was before Brian's time, but to whittle down a bit in terms of what we had in the net funds remaining over the course of a multiyear plan that's in the Commitment Plan. And so this is right on target, as Brian mentioned, with that plan, with the multiyear plan and how that would be kind of ratcheted down with some conservatism of holding onto a little bit for what
could be available for additional funds for things.

DR. FERNANDEZ: So you, too, would say good amount?

DR. COOK: Yes. It’s consistent with the plan.

DR. FERNANDEZ: Can I ask Bob and the -- or whoever’s from the FAC here, whether you also see it as not too big, not too small, good amount?

DR. ZWOLAK: Well, I could follow up and of course my question and comment is related exactly to that. So the timing is wonderful, if that's okay.

Let me start by saying, I think the very best number on the page we're looking at is the total awards payment proposed budget in FY '23 of $350 million, which in real hard, already committed dollars, represents a $55 million increase over fiscal year '22.

That proves without dispute that we are ramping up our awards to research. So that's wonderful news.

The answer to Alicia’s question I think is really important because in the past, in the very
recent past, that number of uncommitted funds was
potentially as high as $600 million. And I think
all of us would think that number is too high.

And so, I see -- two things. First, the
number of $200 million really means that we need to
continue ramping up. But it means -- and we fell a
little bit short this year, although it did
increase, but we fell a little bit short of our goal
this year. But it means next year we have to work
even harder to find meritorious comparative
effectiveness research to invest in.

But I do think that 200 seems like a
reasonable cushion and that perhaps the first part
of your question about inflation, may in fact be an
indication for use of those funds for already
committed research if inflation continues to be
substantial. And so, I'm much more comfortable, I
think the discussion we had at the FAC supported
that, that we're much more comfortable with a
cushion of uncommitted resources in the $200 million
or less category.

Certainly much more appropriate than twice
or three times that.

CHAIRPERSON GOERTZ: All right. Thank you, Bob. Did you have any other comments that you wanted to make Bob? And Nakela, or Brian, did you want to comment a little bit more directly on Alicia's question about whether you're hearing from investigators that there are some impacts of inflation?

DR. COOK: I don't have a kind of systematic sense of that right now, Alicia, but you know, I know there has been some discussion about the issue amongst some of the program officers, but don't really know to what extent they're really hearing that as a loud and clear signal.

You know, we also have been in many ways finding ways we track what we hear from our research community who have applied and been awarded PCORI funds. And so during those assessments, that can be something we could potentially think about adding in given the unique time that we're living in. But we have those kind of routine assessments that give us that opportunity to do that.
CHAIRPERSON GOERTZ: Thank you. All right, Mike.

DR. HERNDON: Brian, a point of clarification. Where do PCORI salaries fall?

MR. TRENT: They fall in two places. They fall in the total program and program support and also total administrative support.

DR. HERNDON: And how is that determined? Which bucket?

MR. TRENT: The total program and program support are those that are directly, individuals who are directly, involved in programmatic activities. The administrative support would be places like my office, Office of the General Counsel, but those are where those salaries occur.

So the individuals that are involved in -- actually be looking at the awards and those type of things, they're the ones whose salaries are in program and program support.

DR. HERNDON: Got it. Thank you very much. And does program support also include experts outside of PCORI that we call on for advice
and review? That’s also is in program support?

MR. TRENT: Yes. Right.

DR. HERNDON: Okay. Thank you very.

CHAIRPERSON GOERTZ: All right. I believe

Russ has a comment. Russ, you still with us?

DR. HOWERTON: I just wanted to reply, that

I completely agree with Bob as a member of the FAC, the answer to Alicia’s question.

CHAIRPERSON GOERTZ: Great. Thank you.

All right. Bob V.

DR. VALDEZ: I just wanted to say that's always the two lines that I always look at, program support and administrative support, for a research institution. And 22 percent falls well in line with an institution of, certainly, this size and the kinds of awards that are given. So keeping track of those two lines is always something that I always like to keep an eye on.

And it looks like you're doing a good job of sort of projecting what you need to make the program work.

MR. TRENT: Thank you.
CHAIRPERSON GOERTZ: All right, thank you.

Any other comments or questions?

[No response.]

CHAIRPERSON GOERTZ: All right. In that case, I'm going to ask for a motion to approve the proposed FY 2023 PCORI budget.

DR. LEVINE: So moved.

CHAIRPERSON GOERTZ: All right Sharon.

DR. FERNANDEZ: Second.

CHAIRPERSON GOERTZ: Alicia, as a second.

Is there any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All those in favor, please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[No response.]

CHAIRPERSON GOERTZ: Abstentions.

[No response.]

CHAIRPERSON GOERTZ: Okay. Thank you. Great job, Brian.

MR. TRENT: Thank you.
CHAIRPERSON GOERTZ: Thank you so much.

All right. We are going to move into our next agenda item then, which is to consider a new proposed governance framework for approval.

So we'll be hearing from Kathleen Troeger today, the Chair of our Work Group to Optimize Effective Governance and Board Engagement.

This work group, just as a reminder, was developed in March of this year, with the aim to develop an evolved approach for the Board's strategic oversight that advances PCORI’s new Strategic Plan and our reauthorization priorities.

So I'd like to ask Kathleen to make some brief remarks and then Nakela to present the overall governance framework. And then, I look forward to a robust discussion before we consider a motion to approve.

So, Kathleen, I'll turn it over to you.

DR. TROEGER: Thank you, Christine. It has been a remarkable opportunity to work over the last six months really with this cross-functional group, including yourself and fellow Board members, Alicia,
Russ, Sharon, James, Danny, as well as PCORI staff, Nakela, Harv, Michele, Mary, and Maureen. I see everybody sort of heads down, but thank you very much for really all of your efforts.

It's been those sustained efforts, the collaboration, the engagement, and really the act of participation that have advanced this work. Nakela has provided us an overview during her Executive Director report, which address both the purpose and the desired outcomes from the work group, which has really, you know, we firmly believe that they have addressed both the governance challenges and proposed a new governance framework for us to consider and we're bringing to the Board today.

So with that, and without any further delay, I want to provide the work group’s support and endorsement and the recommendation to be considered by the Board and turn it over to Nakela for the presentation. Thank you.

DR. COOK: Thank you so much, Kathleen.

I'm excited to present the proposed elements of the governance framework that the Board
will be considering for approval. We can move to
the next slide.

We've outlined here the main elements of
the proposed framework, and they're displayed on
this slide just for a quick at a glance look, and
you can see here that the Board of Governors would
continue to operate to provide strategy and policy
direction, and have standing committees, including
the Selection Committee, the Finance and
Administration Committee, the Governance Committee,
and the Executive Evaluation and Compensation
Subcommittee, as well as a new Strategy Committee
and ad hoc working groups formalized into this
governance framework.

The Board could charge the new Strategy
Committee to perform specific and ongoing strategy
functions at an early and nascent stage of new and
emerging concepts and ideas in this framework. The
Board could also task more specific things to an ad
hoc work group for short-term, very specific
engagement in an activity that's further along in
development. And both of these opportunities
provide for a mixed perspective from Board members, cross-functional perspectives, to bring to bear on concepts, ideas that may be emerging for important discussion.

All of these aspects of the governance framework, the committees and the ad hoc work groups, would then report back their recommendations to the Board in this framework and structure.

We can go ahead to the next slide.

The quick summary of the proposed framework is outlined here on the slide, and this is what would be considered for approval by the members of the Board of Governors, that we retain the following standing committee structures, including the Governance Committee, Finance and Administration, Executive Evaluation and Compensation, and Executive Committee.

That we create a new standing Strategy Committee that can further engage in strategic discussions as tasked by the Board, related to items of ongoing importance, and that we pause the convening of the three current standing strategy
committees, including the Engagement, Dissemination and Implementation Committee, the Research Transformation Committee, and the Science Oversight Committee, while the new Strategy Committee is being implemented, and that we expand the Standing Selection Committee to allow it to consider additional types of awards, including comparative effectiveness research awards, dissemination and implementation awards and research infrastructure awards. And that we formally incorporate ad hoc work groups into the governance framework given the success we've seen in piloting some of those work groups over the past year or two.

And that we assess the model, the new governance framework, to determine if it's working and if it's achieving the desired outcomes and adapt and adjust as need be through that assessment.

So this is the proposed framework that is being put before the Board for any discussion and then consideration for approval. I'll turn it over to you, Christine.

CHAIRPERSON GOERTZ: Thank you Nakela and

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Kathleen for those remarks and overview. Just as a reminder, even though the working group has been committed diligently to this effort since March, this is actually something that has been evolving over the past two and a half years. Beginning with our work to develop a governance culture and then to begin to look at how implementation of that culture may impact our current governance structure and what changes needed to be made.

We first began talking about this proposed governance framework as a board last December with continued discussions at our meetings in March and then again in June. So it has been really exciting to watch this concept evolve over time based on the work, the incredible work of the work group, as well as the input that we've gotten from the Board all along the way. And I'm really excited to have this discussion today and then to bring this to a vote.

And I see that Mike has his card up. So why don't we just jump into the discussion, Mike?

DR. HERNDON: Thank you, Christine.

First of all, much appreciation, Kathleen,
to you and the team and the work group for this very important transformational work for the Board.

My question, Nakela, I think it's best suited to you and by the way, I fully support this governance framework proposal. The makeup of the Executive Committee currently is based upon existing committees that are no longer going to exist. So what will the makeup of Executive Committee look like in the new governance structure?

DR. COOK: One of the key next steps following potential approval of this framework by the Board of Governors, would be that the Governance Committee takes on quite a bit of work in thinking through some of the implications for transition. And this is one of the types of things that the Governance Committee would take on in considering and deliberating what the appropriate next steps would be to propose back to the Board a potential way in which we may fulfill the responsibilities of the Executive Committee with this new framework.

And so, it's anticipated that the Governance Committee would focus directly on that.
point as well as several others. And there are many different options in terms of thinking through what an appropriate kind of appointment for the Executive Committee might look like.

Right now, as Mike is referring to, for other Board members, it's ex officio appointments of the Chairs of the current strategy committees. And so there are iterations of that based upon the new framework that the Governance Committee can consider.

CHAIRPERSON GOERTZ: Nakela, correct me if I'm wrong, but my understanding is that if in fact the Board does vote to move in this direction, that by pausing the three current standing strategy committees, there would still be a Chair that would be able to serve on the Executive Committee in the interim while these decisions are being made, is that correct? In the interim?

DR. COOK: That's right. So there's no --

CHAIRPERSON GOERTZ: Gap.

DR. COOK: That's right.

CHAIRPERSON GOERTZ: Okay. Thank you.
Did you have anything else, Mike?

DR. HERNDON: I think the last 15 or 20 seconds was kind getting it what I was --

CHAIRPERSON GOERTZ: Okay.

DR. HERNDON: Since we don't have a, you know, governance in this new structure established yet, just what is the -- yes, that answered it.

Thank you very much.

CHAIRPERSON GOERTZ: Okay, thank you.

Kathleen.

DR. TROEGER: Just to clarify, and Mary, I'd encourage you to jump in here. I hear some -- I just want to make sure we're not conflating Executive Committee, which as it stands now, with a new Strategy Committee. Okay.

Because some of the language in our discussions just leads me to believe that's an important point to clarify.

CHAIRPERSON GOERTZ: And just a reminder, while it's incredibly important that we make sure that we have -- that our Executive Committee would be fully operational if indeed it was called to
order, it has never yet in PCORI's history been
called to order because the entire -- the issues
that would -- might normally go to an Executive
Committee, in our case, come to the full board.
And so, the Executive Committee is really intended
to be for PCORI emergencies. We have not, I would
say there have been times when perhaps we've come
close, but we have not ever had to convene that
committee.

All right, anyone online -- that’s joined
us online, who has a question or like to make a
comment?

[No response.]

CHAIRPERSON GOERTZ: Is anyone on mute
trying to make a comment?

[No response.]

CHAIRPERSON GOERTZ: All right. In that
case, Maureen, before I call for a motion, I'm going
to ask if there are any updates to Board member
attendance that we should be aware of.

MS. THOMPSON: No changes, other than that
Russell Howerton joined us during the Budget item.
CHAIRPERSON GOERTZ: Great, thank you. In that case, I am going to ask for a motion to approve the proposed governance framework.

DR. SCHUSTER: [Signifies motion.]

CHAIRPERSON GOERTZ: James Schuster. Can I get a second?

DR. TROEGER: [Signifies second.]

CHAIRPERSON GOERTZ: Kathleen. All right. Is there any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All those in favor, please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: All right. Opposed?

[No response.]

CHAIRPERSON GOERTZ: Abstentions?

[No response.]

CHAIRPERSON GOERTZ: All right. The motion passes. Thank you.

A very exciting moment for a process that has been ongoing for quite some time. And so, I'm very excited about this.
We are now poised to take a 15-minute break. I think we'll go ahead and do that. I think we probably will -- do we have to wait until 11:10 to adjourn or should we, or I mean to come back to order? Should we come back to order in 15 minutes?

UNIDENTIFIED SPEAKER: Yes.

CHAIRPERSON GOERTZ: In 15 minutes. All right. And because there's no public comment, I think we have a little bit more flexibility, so we will reconvene at 10:45. Thank you.

[Recess.]

CHAIRPERSON GOERTZ: All right. We're going to go ahead and get started again. So what I'd like to do is, actually I'd like to ask Bob to come back.

[Laughter.]

CHAIRPERSON GOERTZ: Well, when Bob comes back, he as Chair, and Kara Ayers as Vice Chair of the PCORnet Priorities Work Group will introduce our next agenda item, which is to Consider Proposed Strategies to Leverage PCORnet to Advance PCORI’s National Priorities for Health and to Evaluate
PCORnet Performance. And without further ado, I will ask first, Bob, and then, Kara, to make some comments.

DR. ZWOLAK: Well, thank you very much, Christine. This is a very exciting time for me and for Kara and Erin, and I think in the rest of the PCORnet Work Group, to present this information.

And the first thing I'd like to do is probably go to the next slide, which identifies the members of our work group. So thank you for all the hard work to Kate Berry, Alicia Fernandez, Christopher Friese, Russell Howerton, Mike Lauer, Barbara McNeil, and Danny van Leeuwen, who helped us immensely through this effort and spent lots and lots of hours, many of them on late Friday afternoons, were extremely challenging to get this work done so Stage Two of this PCORnet Work Group went very well.

I'd like, from the hundred-thousand-foot level, to say that our charge was really twofold. One was to consider strategies for evaluation of PCORnet and the other was to consider strategies for
moving forward for PCORnet, itself, in terms of research, and we have lots of important information. I think the evaluation piece, we ended up thinking that evaluation needs to be continuous, nonstop, and provided by a combination of internal and external views.

I think our take-home from the strategy for research is that there are so many opportunities for what PCORnet can do, that we really have to focus. I mean, if we want this to work and continue working well, it’s an amazing tool, but we really do have to decide what we’re going to focus on. Because when we started to consider the opportunities for PCORnet, they’re just immense. We could look anywhere with it, and we can, but we have limited resources, and so we have to in fact, focus.

So those are I think, the two biggest take home points.

And since this is my last meeting, I’d like to just make one example. I’m not sure if any of you saw in the last day or two, the JAMA Network identified or published a trial of gabapentin use,
perioperatively. So as we all try to get away from opiates, perioperative gabapentin has been very commonly employed to the fact that gabapentin, at least according to this report, is currently the tenth most commonly prescribed medicine in the country. It's amazing.

And this report was retrospective. And so even though it was propensity matched, you know, in theory propensity matching is sort of the best retrospective study one can do. It's still retrospective. And so, it's open to those kinds of criticisms.

And it was done on the Premier Healthcare Network, which perked up, you know, perked up my mind as being not real competition for PCORnet, but sort of in the same category, hundreds of thousands of patients. And in fact, they found patients who got perioperative gabapentin had higher incidence of postoperative delirium, had a higher incidence of pneumonia, and had a higher incidence of the need for new antipsychotic medications.

So not what we would necessarily think is
that as the best gift to an alternative to opiates. And we could, PCORnet could look at this, and with our networks, PCORnet could do a prospective study and really get definitive information about this in an area where we really need more information. Alternatives to opiates, perioperatively and postoperative, is a crucial opportunity.

We could do this in a few heartbeats and it just seems like that's just one of hundreds of potential comparative effectiveness studies that PCORnet is ideally suited for.

So I'm very enthusiastic. I'm anxious to hear this report. The work group put in lots of effort and I think we have some good ideas for you. So Erin, please proceed.

Oh, I'm sorry.

DR. HOLVE: Kara.

DR. ZWOLAK: Kara, I'm sorry. I apologize.

DR. AYERS: That's all right. You're so excited.

[Laughter.]
DR. AYERS: I want to thank Bob for his leadership. I've learned so much, not only about, but also from your leadership style and strategies to move us through some really difficult work. So it was an honor to work with you on what's, I guess, your last work group, officially.

I also want to thank the PCORI staff that helped us. We had a lot of hard work going in, between meetings, during meetings. So Erin, thank you, Kim, Claudia, Rachel, Laura, and Nakela. Thank you to those Friday afternoons we were working hard. This group was extremely collaborative and engaging, I think you're going to see that reflected in the priorities. And when I think about what I hope for the future of PCORnet, you know, I hope that it becomes less of this nebulous kind of extraneous thing that is hard for us to wrap our heads around. As we've really grappled with this together, I think what's become clear for me, is that there's real potential for data equity moving us towards having better answers to comparative effectiveness research questions.
And those are really at the heart of what the big questions that we have as, not only patients, but our other stakeholder groups. But patients, particularly, stand in the front of my mind in terms of that PCORnet is hard for us to explain and for different groups to understand but it really, I think, holds the key to answer some of these really important, impactful questions.

So thanks to all that have gone into this work and let's hear the plan from Erin.

DR. HOLVE: Well, thanks so much again, Bob and Kara, for your tremendous leadership on this work group. And that was really bittersweet Kara, when you said, Bob, this is your last work group. So thank you again. And again, my sincere thanks to the whole work group for their dedication, deliberation, and an impressive final work product, which I'm pleased to present on the work group's behalf.

So as Nakela mentioned this morning in a brief reminder, the Stage Two Work Group’s activities are grounded in work that was completed
by the Board in 2021 to develop a set of prioritizing principles for infrastructure funding relating to PCORnet. These principles really promote PCORI's focus on patient-centeredness, the national scope and comparability of PCORnet data, and its use for studies that are national in scope, as well as governance and partnership of the network.

So it's important to remember that these principles were used as the foundation for the current Phase 3 contracts for the Clinical Research Networks, as well as the Coordinating center and guide all the work that the PCORnet does.

The focus of the stage two efforts, on the next slide please, was to get more specific and strategic to express the Board's strategic approach to both evaluating the accomplishments as a network that are due to PCORI funding and to inform discussions about future PCORI investments that will maintain and enhance PCORnet, as well as proposing crosscutting strategies to integrate and leverage PCORnet in ways that advance PCORI’s National
Priorities for Health. Because strategic priorities naturally flow into evaluation strategies, I will discuss the Board work group’s recommendations in this order.

So on the next slide, please, and then actually we can skip to the one after that.

To help frame this discussion it’s useful to note that the strategies document presented to the Board for a vote includes four major strategic pillars and three approaches to evaluate PCORnet’s performance, and Bob alluded to some of these earlier.

So as you can see on the left, consistent with the Board’s focus in the prioritizing principles on using PCORnet for research, the first of these strategies as a set of efforts on funding or a set of strategies on funding research. The second focus pillar is on investment strategies for the infrastructure that will both enable PCORnet to be well-maintained and to innovate. The third is addressing strategies to expand uses of PCORnet for research. And the fourth, is increasing the use of
PCORnet for PCORI’s operational and strategic priorities.

The evaluation strategies then flow from these cross-cutting strategies and focus on specific approaches to continuous monitoring, specific priorities and approaches to evaluate performance, and a focus on aligning PCORI’s organizational learning strategy and some efforts to assess the maturity of PCORnet.

Next slide, please.

With respect to the first pillar focused on research funding, the Board work group had extensive discussions about the need to balance PCORnet’s intentional design as a disease-agnostic network with the current needs of the organization that is based on the 2019 Authorizing Law. As a result, the work group elected to focus on funding research that uses infrastructure to conduct definitive studies that advance the National Priorities for Health which was part of the prioritizing principles and maintain the broad focus, that disease-agnostic focus, while also calling specific attention to
research on intellectual and/or developmental disabilities, maternal morbidity and mortality, health equity, and rare disease research.

Next slide, please.

With respect to the second pillar, focus on supporting the infrastructure PCORnet that would be both capable of continuously learning and improving while also innovating. The work group emphasized the need to, first of all maintain baseline network functions that enhance data quality and network research capacity to support studies. Again, with that focus back on the research.

Second, to accelerate participation of diverse, underrepresented, and underserved populations, both in governance and research. And I think this speaks in part to Kara's comment about data equity earlier.

Third, to support PCORnet coverage so that the network is comparable to the general United States population. Maintaining that commitment, again, to data equity.

And then fourth, innovating to advance
PCORI’s National Priorities for Health, including enhancing data capacity in areas such as social determinants and patient reported data, as well as promoting open science approaches that accelerate progress towards an integrated learning health system.

Concluding this set activities, the focus was on enhancing an engagement infrastructure that supports meaningful patient and stakeholder partnership in all stages of research.

Next slide, please.

With respect to expanding the use of PCORnet by enhancing understanding and activities to make full use of the network, there was a discussion and a strategy that focuses on both, improving the visibility and stakeholder understanding of the unique capabilities of the network, really is a transformational resource. This includes PCORnet capabilities supporting the full trajectory of research across a range of studies that may include platform trials, pragmatic trials, and high-quality observational studies, such as the example that Bob
The second piece here was promoting the access and use of PCORnet by a range of users, including researchers, patients, caregivers, communities, health systems, as well as other health stakeholders. PCORnet, as you all know, is open to all researchers who are pursuing relevant questions in alignment with the National Priorities for Health and the team supporting the front door are ready to answer questions and support via PCORnet.org.

The third component here was opportunities for greater partnership with organizations that support research using PCORnet that, again, is aligned with PCORI’s strategic priorities. This is part of the initial design of PCORnet and our contribution to the public good. And several of the examples Nakela discussed in her opening remarks this morning illustrate where this type of “powered by PCORnet” research is having a significant impact.

The network can and is being used by other funders to support health research such as the CDC’s surveillance activities for COVID-19. And there was
a strong interest among the work group in seeing this effort continue and expand.

Last, but certainly not least, the work group felt that as part of supporting research funding using PCORnet to build awareness of the capabilities in PCORnet, it's also important for PCORI to increase the use of PCORnet for our operational and strategic priorities, such as identifying potential gaps in research or data or knowledge, and to inform the development of our funding announcements.

Next slide, please.

Turning to the evaluation strategies consistent with best practice, the Board emphasized the need for continuous monitoring and evaluation of the network, both to contribute to network partners capacity to continuously learn and improve. Inform the Board's strategic planning and decision-making about both, baseline network functions and the innovation and expansion efforts, as we've discussed, and to assess the performance both for the network as a whole, as well as all the
participating network partnerships acknowledging that dynamic and federated model.

Next slide, please.

The work group also spent time discussing strategies for evaluating performance, which focused on prioritizing better and faster over simply cheaper research, emphasizing efficiency, but being, again, focused on the better and faster aspects of this transformational network with respect to network capacity.

In addition, there was focus on considering the evaluation needs and perspectives of a diverse group of stakeholders in the PCORnet ecosystem. This includes everyone from PCORI staff to the participating CRNs and health systems, and importantly the patients and communities within the PCORnet users, as well as potential users in the future.

And lastly, an aim to benchmark PCORnet performance against appropriate comparators wherever possible, which remains an important focus among the Board work group members in their discussions.
Of course alignment was also considered important. So on the next slide, please.

The work group focused on a strategic approach to evaluation that aligns with PCORI’s existing organizational learning strategies and the National Priorities for Health. In addition, the work group agreed that given the complexity of PCORnet, a maturity model would be appropriate for evaluation. In these models, specific domains such as research, data and technology, and engagement are each evaluated independently, though in the context of the whole, to assess the maturity of each domain and assess opportunities for continuous improvement.

There are several relevant maturity models in the health research space and the work group agreed that these provided confidence in this approach.

So that concludes my remarks, but before I end, I wanted to offer again my great thanks to the PCORI Priorities Stage Two Work Group. It has been such a sincere pleasure to work with the Board on this effort and the PCORI team who, as Kara said,
have been tireless and working collaboratively on this effort. I greatly appreciate all the members' thoughtful participation and work to develop the strategies.

Again, a special thanks to Bob and Kara for their support and leadership. And Dr. Goertz, I'll turn the item back to you.

CHAIRPERSON GOERTZ: Thank you so much, Bob, Kara, and Erin.

Before we begin our discussion, are there any Board members who believe they should recuse themselves from this deliberative discussion and vote on PCORnet?

DR. TROEGER: Yes, Kathleen Troeger recusing herself.

CHAIRPERSON GOERTZ: Okay. Thank you, Kathleen. Duly noted.

All right, in that case, I'd like to invite members of the work group to share their thoughts before opening the floor to the full board. Danny.

MR. VAN LEEUWEN: Thank you. I want to say something about why I wholeheartedly support this
plan. My concern joining this group and thinking about PCORnet is that I was committed to the increase of using an infrastructure, like PCORnet, to further public health research, and that there was considerable, that would require a considerably different approach.

So, for example, right now, it, we talk about PCORnet as if it's a monolith, but it isn't. There's PCORI. There's the Duke Coordinating Center. There's the leadership of the Federated Networks. There's the Steering Committee. And I think that we don't talk about, there's the EMR vendors, who have considerable control over clinical data that's available.

And that there are initiatives out there working on expanding standardized data sources like HL7’s Gravity Project, like the Social Intervention Research and Evaluation Network, the National Birth Equity Collaborative, the Public Health Association, and cybersecurity experts develop a big database. You know, there's cybersecurity.

So anyway, I think that we chewed on this
stuff and I think to me the Friday evening was the least of it. It was -- these are hard issues and real challenges to think about implementing. And I feel like through discussion and negotiation we came to, and the staff -- you know, every time there was another meeting, there was another iteration bringing in and trying to synthesize, you know, the sometimes awkward conversations or whatever.

And that each iteration was more clear and more representative and I think, although I think, this is going to be like a challenge to implement this is a great foundation and I supported wholeheartedly.

CHAIRPERSON GOERTZ: Thank you, Danny. Any other work group members? Anyone on the -- who's joining us virtually?

[No response.]

CHAIRPERSON GOERTZ: Okay. Bob, if there are no other commentors, Sharon, do you want to comment? If there are no other commentors, I'd like to add one piece to this and that's the question about operational excellence and for lack of a
better word, productivity and marketing.

Because PCORnet is a network of networks and basically everyone involved in PCORnet, to some extent or another, has a different day job. I think if we, PCORI, want PCORnet to succeed, we've got to be the ones to keep the eye on the ball and keep PCORI working and looking for new research, looking for improved methods to determine social determinants. We know -- we've reviewed a nice white paper that suggests it's possible, but it's not going to be easy.

And I think we need to be the driver here if we want this to be successful. And it's not just the evaluation strategies. The evaluation strategies are sort of a retrospective look at how well it's done, which is really important, but in terms of making this a longstanding success, I think PCORI needs to provide the energy and the enthusiasm and as well as a direction, I think is much helped by this outline and these goals.

But I think this is PCORI's biggest single effort so far, certainly in terms of dollars and
magnitude and everything else, creativity. And so,
I with the pause of the RTC, which was sort of the
committee of record keeping track of PCORnet, I
think it's going to be really important that we
determine what subgroup, work group, strategy
committee pays attention to PCORnet in this new
phase. Thank you.

CHAIRPERSON GOERTZ: Thank you Bob.

Sharon, then Bob V and then James.

DR. LEVINE: Bob preempted my part of my
comment/question, which was if there is a single
thing we've talked about over the last couple of
days that deserves a home and a permanent home, it's
the PCORnet. And I think, you know, as you all move
forward, thinking about where that is, where that
lives, is going to be really important.

The question I had was, did the work group
think about at some point evaluating whether the
current governance model of the PCORnet actually is
still fit for purpose, or whether there needs to be
some reconfiguration or realignment of that?

And it goes to your comments, Bob, about
marketing, about ownership, about promotion. And to me, I'm channeling Alicia here, ensuring that the values, that PCORI’s values, remain embedded in -- and the priorities, remain embedded in the approach to who gets to use PCORnet for what.

CHAIRPERSON GOERTZ: Thank you, Sharon.

Erin or Nakela or Bob?

[Off microphone discussion.]

DR. HOLVE: Thanks Bob. So Sharon, it’s a fantastic question and there certainly was some discussion of that. I gather your question extends beyond sort of PCORI's Board governance to the governance of PCORnet. Is that correct?

So we certainly have been looking at those issues in talking with the PCORnet Steering Committee, as you know, in Phase 3, now PCORI staff has a vote on that steering committee. Though, again, it's important to remember that that steering committee is not, you know, binding with respect to decisions that the network makes, so it does not make any financial distinctions because all of the contracts really provide the oversight for
activities with PCORI.

Where this gets challenging, and I think merits some ongoing discussion, is the partnership model. And we want PCORnet to be used, again as Nakela offered, some very compelling examples this morning by other funders and we want that to be a flexible and living approach. So I think that there's going to be an ongoing evolution there as well and something we're very committed to.

And again, that I believe the strategies that are before the Board for consideration to vote will help us work to evolve.

I don't know, Nakela, if you want to add anything.

DR. COOK The only other thing I may add is that when we were talking about governance with the work group, one of the things that we emphasized is that even the work we're doing in the work group, the work that's happening today as part of the governance in terms of thinking about the strategic direction for PCORnet, and so, it was integrated in the way in which we were thinking about governance,
but we also spoke quite a bit about the fact that the way in which PCORI's priorities remain embedded and prioritized for PCORnet really stems from our funding strategy. And so, we fund based on the strategy that's discussed with the Board of Governors and the strategic priorities there, and then we provide the contracts consistent with that strategy and oversee them for execution against that approach.

And so, our funding line is really one of the strongest ways that we continue to maintain that PCORI direction in the work of PCORnet.

CHAIRPERSON GOERTZ: Bob, did you want to make any comments?

DR. ZWOLAK: And if I could add, I agree with absolutely both of those, but I do think that as we talk about evaluation, one of the evaluation issues at a high level may be the governance issue.

And while we talked indirectly, many of our discussions were revolved around these issues of governance, none of them were squarely aimed at governance.
CHAIRPERSON GOERTZ: Great, thank you. Bob V.

DR. VALDEZ: Thanks very much. And Bob, thank you for raising this issue about really having PCORI drive PCORnet if it's going to be successful in the longer run. And Sharon, as usual, you've tapped the main issue, which is how does this partnership actually govern itself and if it's going to carry the “PCOR” part of the name, how it remains true to the PCORI set of values and focus.

I don't know enough about it, so I'm glad, I just wanted to say, I'm glad this discussion is taking place because it's one of the things that I was left trying to scratch my head about and trying to understand. And I think it's worth, and as others have said, a longer discussion and more thoughtful consideration.

CHAIRPERSON GOERTZ: Thank you. James?

DR. SCHUSTER: Yeah. Thank you. I agree. It was definitely a helpful overview and all these discussions are helping me gradually get a better enhanced sense of the PCORnet work. Kind of
1 building on Bob's comment, you know, when we look at
2 the metrics that you've proposed for evaluation, I
3 wondered if one metric really is kind of above the
4 rest, which is funded CER tied to PCORI’s priorities
5 and that all the other activities really are -- not
6 entirely, but probably largely in service at that.
7
8 And so, I wondered if we want to wait and
9 track that explicitly, you know, in the same way
10 that we look at a number of CER studies funded, you
11 know, number of them published in a high impact
12 journal, results published in high impact journals,
13 et cetera. If that's a metric that we really want
14 to highlight in terms of looking at the impact of
15 the funding for PCORnet.
16
17 DR. COOK: Thanks so much. It's a helpful
18 suggestion. And I'll also note, I think Laura
19 Forsythe, the Director of our E&A Program, is on the
20 line and the Laura's team is really going to be
21 leading the evaluation effort. So I didn't know,
22 Laura, if you are with us, if you wanted to add?
23
24 DR. FORSYTHE: I am. And I think that's a
25 great comment. I really appreciate it. I think
that resonates well with the discussions that the
group had over the many meetings with respect to
where the focus needed to be and how to prioritize
our efforts. So we'll look forward to carrying that
through. Thank you.

CHAIRPERSON GOERTZ: All right. Thank you.

I've got Alicia and then Mike.

DR. FERNANDEZ: Thanks, and thank you for
this, all the work that went into producing this
report. It was well-presented and I, for one, you
know, I look at those priorities and I'm like, yep,
those all sound -- those all sound right.

What they also, however, what I don't have
a handle on is that -- is how we're going to not
essentially choose among them, but how we're going
to invest among them, and how we're going to space
that out over time. So, for example making PCORnet
more representative of the U.S. population is an
important goal. On the other hand, there may need
to be -- there definitely needs to be more
investment in being able to produce better data or
different levels of data.
So, I feel that the committee has done great work, but I would like to hear a little bit more on if you could help us move forward in the sense of, I don't know -- I don't have a sense, and of course, it's reasonable that where we're going to have these discussions, how these decisions are going to be made, whether we're talking about a three-year plan or a four-year plan or a two-year plan, you know, and whether or not you considered any recommendations either for governance or for more immediate local target of funding.

DR. COOK: I may just open it up for a couple of comments from Erin and then be happy to circle back around.

You know, I was thinking about some of the activity that stemmed from the first, Stage One Working Group, that spawned several kinds of convenings with the community around certain areas, including the social determinant space that the white paper stemmed from and how there are efforts that I think the priorities set up for us that then require a little bit more of that kind of further
digging and information gathering, et cetera. That what I think was very successful was the ability to then bring that back to the Stage Two Committee, Stage Two Work Group and talk about what we learned and then the next step was a more refined strategy approach.

And so, I think that process worked well before and that we may still have the need for that kind of work where we take some of the strategies that are been put forward here and we start to garner the information on what it would take, what would that look like, et cetera, and be able to bring that back to the Board for more discussion and anticipate that's going to be something that's ongoing in discussion. And the Board may want to suggest at that point that perhaps a strategy committee, or something, continue to hear some of that. And so, that would be our first approach would be to bring some things back to the Board following the strategies that have been laid out in order to determine how we move with it next.

Did you want to add anything?
DR. HOLVE: Thanks so much, Nakela, and again, fantastic question, Alicia. It's something I've spent a lot of time thinking about. I know that Kim Marschhauser and Claudia Grossmann, who are the Associate Directors working with PCORnet, do as well.

So I'll just add a couple of quick things for those who have been less involved in the work group, you know, we have about a two-year time horizon with the existing contracts in which we can make some modifications and updates with the current network structure. And so, really there's a good timeframe, I think, in about the next 12 months in which, you know, some of those sort of tweaks and adjustments that the strategies would guide us towards, would address. And then in addition, we'll start to come back and have a conversation about what's the capacity then, potentially for a Phase 4.

So again, for those who are not part of the work group, I just want to kind of outline that general timeline.

In that context, as Bob alluded to, and I
think Nakela just did as well, these reports on the social determinants of health data, alignment and linkage with claims data, as well as patient reported outcomes, and patient-generated data are now really ready for prime time. And so one of the things that we've been working towards, I think we're just about poised to release, is more of a sort of call for comment on some of the recommendations that have been presented in that work. So it's really robust, excellent discussion of the existing data capacity and where we might go next.

But to your point, Alicia, I think figuring out from the research community, what do they see a need to be built or enhanced now to, you know, facilitate the research that they most want to do in these spaces is part of the effort that Bob described, I think around selecting, right -- prioritizing where we go from here. And as Nakela said, that's feedback we can bring back to either the work group or the Board as the preference of the Board moving forward. So I think are a couple
strategies we can take.

CHAIRPERSON GOERTZ: Thank you.

DR. ZWOLAK: Can I add to that as well?

CHAIRPERSON GOERTZ: Yes, please.

DR. ZWOLAK: I mean there's some synergies here. So for instance, if we are to scientifically approach maternal mortality, PCORnet has to have a more representative population so we, PCORI, can emphasize by our funding and our bully pulpit, the importance to do that. And likewise, if we're to be successful in assessing maternal mortality, we need to have better tools to measure social determinants of health. And so those things converge and we can drive that with our funding, which is a huge tool, obviously.

But I do think that it's got to be, I feel some urgency. I feel, not some urgency, I feel a lot of urgency, that we would stay on top of this and keep this moving. Because again, I don't want to repeat myself, but we, PCORI, are sort of the accelerant here. Without PCORI constantly pushing ahead, I don't think there will be as much
timeliness or otherwise, a sense of urgency from others.

CHAIRPERSON GOERTZ: Thank you. Mike.

DR. HERNDON: Thank you. And again, Bob Kara, and the group, thanks for the tremendous work and great discussion. I couldn't agree more with things that have been discussed, and I do believe this definitely supports our National Priorities, but I just can't help myself in wanting to ask the question and because I truly don't know. But I think maybe there's some low-hanging fruit here, if you will, to use Bob's term.

Representing payers, public, you know, and Medicaid especially, I think there's a lot of data in the Medicaid and public-payer space that we could be leveraging. And I know in Oklahoma State, which I live, is standing up a statewide HIE, so hopefully it can be. So, I just want to make the comment that I don't want us to lose sight, and I'm not quite sure how entailing PCORnet is to public-payer data, but I just wonder if there's not a concept to explore there with public-payer data and outcomes.
I understand that claims data is limited, but I just wanted to say that.

And then the question is, that I can't help myself but ask, is there information within PCORnet that we can leverage to get outcomes data based upon payment methodology and healthcare delivery system design? And can we touch that?

You know, we have many physicians that are employed with health systems. We have incentive-based and non-incentive-based contracts with providers and things like that.

So, again, getting to this passion that I have, and I think I would have to represent the Medicaid space, is there a way to determine if outcomes are different based upon payer strategies in the healthcare delivery system design?

CHAIRPERSON GOERTZ: Thank you, Erin.

DR. HOLVE: Well, thanks so much, Mike. Having just come to the PCORI from a Medicaid agency, I can't help but greatly appreciate your comment. And, you know, and really the opportunity to think at the level that you're describing is one
of the major reasons I came to PCORI and was excited
to re-engage with PCORnet, so I think your questions
are really well-suited and fit in with this strategy
of the proposed strategy nicely.

I can also say from my own experience on
the ground, also having just run a network with an
HIE, that you know, some of the questions that
you're raising -- the data elements you're raising
are not easy necessarily to obtain, the structure of
the contract shifts and so forth.

So I think to Bob's comments, I think this
is an area where we would need to decide to invest
and prioritize, to look at some of those questions.
Again, highly meritorious. I think we just need to
engage in some further discussion about the
questions that are of most interest to the Board.

CHAIRPERSON GOERTZ: Thank you Mike and

DR. McNEIL: Oh, I'm sorry. Sorry.

CHAIRPERSON GOERTZ: Okay. We can hear you
now.

DR. McNEIL: Oh, okay. So I think the
whole issue that Barbara raised about the possible
difficulties with the current PCORnet members in
terms of socioeconomic status and ethnicity in
dealing with maternal morbidity and mortality is a
real one.

And I also think that Russell's comment
about Medicaid or other private/public payer options
is also a real one. And I'm wondering if we should
ask the leaders of PCORnet to actually give us a
breakdown for each of their members, what exactly
the socioeconomic status, the minority status, and
the payer status is as far as they can go, so that
we will really know whether we have a good cross-
section of this country. And as a really aggressive
move, I wonder if we would want to give priority
grants to those particular PCORnet groups that
actually were high in some of the desirable
attributes whose -- that we wanted to reach.

I don't know how you feel about that, but
it strikes me that we are doing what we've always
done. We do men, women, age, old, young, whatever.
And we don't preferentially give credit to any group
that has brought in minority groups by whether it's payer, racial, ethnicity, whatever.

CHAIRPERSON GOERTZ: Thank you Barbara.

Erin, did you want to reply?

DR. HOLVE: Thanks so much. And Barbara it's a tremendous observation that, you know, again, this is an effort to transform the way we do research, and to get it. You know, both the data equity issues that Kara mentioned, as well as really identifying where there are opportunities to engage particularly underserved patients in the country in this research activity.

So I really appreciate those suggestions. You know, we do at the outset at a high level have information by area deprivation index for all of the PCORnet and we can go back and look at those data. They're about 17 percent of participants with 30 million participants who we can touch in a year who are in that fourth level, the greatest sort of degree of disadvantage. And we're also taking, again, a closer look as was discussed with the social determinants of health data to try and
understand those issues in a more fine-grained way.

The other thing your comments highlighted for me that I wanted to make sure the Board knows about, is an ongoing effort to build capacity, particularly within PCORnet, particularly within the areas of MMM and IDD. So there's an active effort across the networks to look at what the capacity of the network is to address many of these questions. And also let us know if they think there are potential challenges with the network structure or data so that we can try to get in a more detailed way at some of the questions, Alicia, that you and Bob were both talking about both MMM and IDD.

CHAIRPERSON GOERTZ: Barbara.

DR. McNEIL: So can I follow up? I don't want to be too aggressive here, but I think I am going to be.

This is a pretty important area and I know we can move on it slowly or fast. We can work on it in a slow fashion or in a fast fashion. And is it possible to get some preliminary information on everything that you've said by, not next meeting,
but the meeting after that? So we actually know how
the different groups, what the structure of the
different groups are in terms of these critical
variables and whether or not we could actually do
something to improve our success by making awards
preferentially to those groups that are more to our
liking?

    I mean, I’m basically asking us to move
very fast here because this is an area which we
could study to death and get nowhere.

    DR. HOLVE: I was just going to mention
Barbara, that I think the efforts of understanding
capacity are just for that intent to inform our
funding strategies. And so, that is, I think, kind
of the step that we’re in now is to understanding
that in order to say what is it that we find there
is a capacity to go after within PCORnet and what
other things might we need to do, thinking about
bolstering that for specific studies of interest in
this space.

    And so the research funding would be the
kind of parallel corollary once we understand more
about what we have in an infrastructure capacity. And so we can drive the research funding in the way that we've driven research funding for other PFAs and other types of things quickly or you know, in a more expedited fashion if we find that there's something we really want to capitalize on.

And maybe I'll just add, Barbara, that we are moving with all deliberate speed. I'm not sure I'd promise you a specific date because I know that the Board cares about precision in the data that we're providing as well as speed. So the better, we'll use the better and faster framework again here. But I can guarantee we'll bring back information as rapidly as we can.

DR. McNEIL: I don't think this is an area where we need second decimal point accuracy to be honest. So in terms of precision, I think two significant figures is good enough.

DR. HOLVE: Very helpful. Thank you.

CHAIRPERSON GOERTZ: Thank you, Barbara.

All right. I am not seeing any other tent cards up. Is there anyone online that would make
like to make -- have the last word?

[No response.]

CHAIRPERSON GOERTZ: All right. Seeing none, in that case, I would like to ask Maureen if there are any updates to Board member attendance.

MS. THOMPSON: There are no changes.

CHAIRPERSON GOERTZ: Thank you. Do I have a motion to approve the recommended Strategies to Leverage PCORnet to Advance PCORI's National Priorities for Health and Evaluate PCORnet performance?

DR. LEVINE: So moved.

DR. HERNDON: Mike.

CHAIRPERSON GOERTZ: Okay, thank you. I heard Sharon first and then Mike as a second. All right. Is there any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All those in favor, please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Abstentions?

[No response.]
CHAIRPERSON GOERTZ: Opposed?

[No response.]

CHAIRPERSON GOERTZ: All right. The motion carries.

Thank you again so much to the members of this work group. I know that this has been a true labor of love over all these many months and I really appreciate your work and be very excited to see how this evolves into action. So thank you Erin.

All right. It is quite a bittersweet moment for me then to turn the agenda over to Nakela as we say goodbye to four outgoing Board members who have been with PCORI since the beginning, including myself and our Vice Chair, Sharon.

So, Nakela, the floor is yours.

DR. COOK: Well, thank you for the opportunity to really have a chance to speak about four of our last founding Board members who are departing the Board. This is their last Board meeting with us today, so it really is a bittersweet moment. While we want to celebrate and recognize an
outstanding 12 years of service that each of them
have given PCORI, we also recognize as a fond
farewell that we'll miss seeing our colleagues that
we admire and have enjoyed greatly working with over
several years.

So today we're celebrating Christine
Goertz, Sharon Levine, Ellen Sigal, and Bob Zwolak.
And together they've really helped us to oversee an
incredible evolution of the organization from a
startup with no staff, to a handful of staff, to now
a mature and well-established organization with more
than 300 staff.

And the Board was here even before the
organization and they spent time, a great deal of
time and energy determining how to interpret and
implement our legislative mandate, including even
operationalizing the focus on patient-centeredness
in some very important ways that have really been
making a mark for PCORI moving forward as this is
part of our funding criteria and makes PCORI unique
in that research funding landscape.

They were all, you know, also very deeply
involved in guiding our very first National Priorities for Research, our first research agenda. and PCORI launched its funding opportunities under their oversight. And I've only had the fortune of knowing each of you for a short period of time over your entire tenure on the Board at PCORI, but you've certainly made an impression and none of those accomplishments would've been possible without each of you.

They're leaving PCORI incredibly well positioned to build on its unique role in the health research ecosystem. And as we implement the bold and thoughtful strategic plan that they helped to usher through just earlier this year, we'll continue to think of them and remark on their service and contributions to the organization.

I just wanted to briefly say a few words about each and then provide them an opportunity to remark on their service as well.

Bob, I thought I'd start with you as a physician and surgeon who's represented that constituency for 12 years on the Board. You've
served on several committees and just tirelessly
given of yourself on the Science Oversight
Committee, including chairing that committee for a
year and as Vice Chair before that. You also served
on our FAC, our Finance and administration
Committee, including as Vice Chair on that
committee.

And in addition to your role on the full
board and your big picture thinking, you've also
been someone who's been able to help us with the
details. From the development of our portfolio to
the specifics about individual research questions,
the insights that we've gained from you and speaking
with you over the years have truly developed
important targeted topics that are important for our
nation.

Your thoughts about our Commitment Plan and
our funding profile have led us to be ambitious in
the way in which we think about things. And we've
also been assessing how we're doing against with our
funding, that's really helped to make sure that the
right questions are being asked and that we're
continuing to push forward with everything we can do for the health of Americans with the funds that really have been entrusted to us and you ensured those principles were embedded in our approaches. So we thank you for that and we fondly remember your years on the Board.

Sharon, I also wanted to speak to your service. You've represented the private stakeholder group for 12 years on the Board, or I should say the private-payer stakeholder group for 12 years on the Board and served as the Vice Chairperson of the Board for the past three years and chaired several committees, served on the EDIC for 12 years, and/or its predecessor, I should say.

And you have always encouraged us to emphasize impact and to think about the impact of our work for those that we serve. You have articulated for us in the best of fashion, how to be bold and how to think about aspirational goals for PCORI, and you've been passionate about making sure our work delivers what we've said it would to patients, communities, clinicians, policy makers,
and others. And so, we're incredibly grateful for your service as well.

I also wanted to mention that in Ellen Sigal's absence today, that she has represented the patient and consumer stakeholder group on the Board for 12 years. She serves with distinction on our Science Oversight Committee, and her creative thinking and ability to push us as an organization to be innovative faster in our approaches and take on some of the challenges that are of most important is really unparalleled and these qualities have served for PCORI well, particularly during the pandemic, when we had to learn how to pivot quickly.

And Christine, I certainly would not want to leave this moment for last, but you have served as the integrative healthcare practitioner representative on the Board for the past -- and Chairperson for the past three years, Vice Chairperson before that. And you have led and served on several committees.

And one of the things that's been really, I think, advantageous to us for your service on all
those committees is that you knew about all the
domains across PCORI and it really integrated well
in your role as Chairperson. It's opened our eyes
to new possibilities on the horizon because you've
been able to synthesize all that you've learned
across the activities and think more broadly about
them.

You've always been willing to go the extra
mile for PCORI and do whatever is necessary to
facilitate our success and PCORI’s success and that
certainly is just exemplified in these last three
years of your role as Chairperson.

So to all of our outgoing Board members, we
are just really grateful for everything that you've
given. We are, I think, in many ways, shocked that
today is already here and know that you'll be missed
in so many ways and we hope that you stay connected
to PCORI.

But we did want to give you a moment for
some of your words reflecting on any fond memories
you may have from your time on the Board, or the
PCORI accomplishments you may must be proud of or
perhaps your hopes for the future or even what you think some incoming Board members may want to hear about time of service on the Board.

    So Bob, I was wondering if you kick us off and let us know some of your thoughts.

    DR. ZWOLAK: Thank you for those kind words. We live in an ever-changing world. And so, it certainly is sometimes a very cruel world, you know, President Putin sees fit to bomb Ukrainians in the homeland of my grandparents. And we live in such a world of hyper-individualism that people get in fist fights at school board meetings and toxic populism is all around us. And in that setting, it’s just amazing to me that the PCORI Board could have come together and have been so successful over time.

    And people, you know, who I represent or who Sharon represents, we sort of all dropped that at the door. Hang up your guns at the door and you know, come in and negotiate and I think we've been very successful in that regard. It's been a great trip.
But my favorite story, or one of my favorite stories forever that I'll never forget is the odd couple of Steve Lipstein and Gene Washington going into a corner Bank of America and saying, you know, they had $10 million they needed to deposit in a new account and they wanted free checking.

[Laughter.]

DR. ZWOLAK: And you know, who is this PCORI thing? I mean, that's just a wonderful story. And now we have this just fabulous new location, which I think will bring us together, bring PCORI together more than ever. So I want to congratulate everyone that helped in finding this new home. This is just terrific.

I think enough couldn't be said about the staff. I mean the staff has been ever, ever, ever improving and the quality of some of our stalwarts who have been here for many years and the quality of the new additions to the staff, I think are spectacular. And when I look at the changing of the Board, you know, it's six, I think six new members you know, you say, well, this might be a period of

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potential speed bumps or even instability. But the fact is that the remaining Board members and the staff are so strong that I think that it won't, you know, there might be a tiny bit of a pause as the new Board members kick in, but the GAO has been very good at picking Board members, at least in my opinion, and so I suspect things will go on and get better and better and better.

I want to point out two things that I think going forward are going to make a huge difference. And the first is our just finished discussion about PCORnet, I think that just has enormous potential to answer lots and lots of really important questions. And so, the advice I would give is to really focus on PCORnet and continue to emphasize the need for its development. You have to, you know, we talked about this a lot in the work group, we have to continue to ensure the basic stuff works. Like, you know, the ability to pull labs and really basic things, and the vastly more complex issues of being able to accurately identify social determinants in PCORnet and make sure PCORnet represents the real
people in our country.

It's very difficult, but I think PCORnet can do it.

The other thing I think is that I want to bring up, just again, is the decision we made very recently about the changes on the Methodology Committee. And I do appreciate Robin and the team with the Methodology Committee, but I think that they've been hindered by the firewalls and the makeup of that group. And now I think that they will be released and I'm happy to hear there are potentially lots of good applicants for the Methodology Committee because I think the Methodology Committee has done yeoman's work at their baseline job of making the standards. But I do think that they can help us move forward with lots of research questions if we engage the Methodology group more.

So I look forward to a very, very rosy future for PCORI. I think that this is a fantastic combination of staff and Board members that have learned over time and with our new Strategic Plan
have the pathway clear to collaborate more and more all the time and make great work of the funds that we've been given.

So, thank you.

DR. COOK: Thank you so much, Bob. And as always, a wise counselor as when I first met you and you leave us with some wise advice.

Sharon, did you want to speak next?

DR. LEVINE: So I could just say what he said because much of what I had prepared or thought about saying, Bob has already articulated.

Nakela asked us to talk about what our fondest memories were of PCORI and as I thought about it, similar to what Bob said, my fondest memories are every time we've had the privilege of getting together in-person. Healthcare is a relationship business. And you know, as wonderful as technology is, there is no substitute for human relationships and my ability to meet you, each of you, and to even our newest members of the Board in whatever context we've been able to meet it has been an extraordinary privilege and the opportunity to
cross paths with people whom I never would've had the opportunity to do so with, other than my service on the PCORI Board. It has just been one of the joys of the last 12 years. Twelve years is a long time.

In terms of PCORI’s accomplishments, I think for me, from my perspective, the things that I think PCORI should be proudest of is in the beginning, soldiering on, in the face of skeptics. We were surrounded by skeptics from every possible perspective. Those who thought we would do too much and those who thought we would do too little and to the great credit of the Board, it never got in the way of keeping our heads down and focusing on the work and trying to do what Congress asked us to do.

The second thing I think PCORI should be incredibly proud of is making good on the promise of keeping patient-centeredness that the core of everything we do. We spent a lot of time in the early days before we had staff debating whether it should be person-centered or patient-centered until
our wise council advised us since Congress made that decision for us, we could end that debate.

[Laughter.]

DR. LEVINE: But I think our recent conversations, and Danny, your contributions to the Board about remembering that this is about people, it's not just about patients, individuals who are ill or dependent on healthcare. And so, I do think the Board gets a lot of credit for keeping that always front of mind, always at the center of what we thought about and did, or think about and do.

And as Bob said, as a board intentionally designed to be diverse and balanced and potentially to neutralize one another's perspective, it has been an extraordinary opportunity. And I've sat on a lot of boards, of watching, as Bob said, people leaving their constituency perspective at the door and coming together to do the right thing for patients. And it's been a joy.

My hopes for the future, continue to do what Congress intended only faster and better. I'm not going to say cheaper. And address the pain
points in the country with great urgency.

I saw today that or yesterday, or today, I can't remember, that HHS released some statistics that we currently have like on average 25 maternal deaths per hundred thousand live births. Three times the number of the top five OECD countries. And the range within the country is enormous.

And 80 percent of those deaths are preventable, or where HHS is determined, are preventable and preventable means we know what would have prevented it. It's not theoretical, it's real.

And to me, this reinforces the need for us to do what we can, for PCORI to do what you can, to address this, as well as the other I'd say public health crises of equity: substance abuse, violence, and the triple threat of anti-science misinformation and distrust, that is a major obstacle to getting the information that we know can help individuals to optimize their health from actually either believing in, trusting, or accessing the services that can be beneficial to them.

Advice to new Board members. Show up and
speak up.

GAO has done a phenomenal job every time in populating this board with talented, committed, mission-driven individuals and our new Board members should not hesitate to speak up, should not wait a year to offer an opinion. This is an environment; this is an effort that depends upon the contributions of everyone involved.

And finally, attend to the Methodology Committee and our partnership with AHRQ. Both of these are critical, haven't had enough presence on the Board's agenda, deserve a lot of investment, and a lot of attention. And among all the partnerships we have, these are two that I think going forward deserve a lot of Board time and investment.

Oh, one more thing. One more thing. I realized today as we were going through the Board meeting that there were no public comments. So we, Christine, Bob, and I can, and Ellen, can continue to contribute and just register as members of the public and --

[Laughter.]
CHAIRPERSON GOERTZ: I had that same thought.

DR. LEVINE: And let you know what we think,

DR. COOK: Well, we'd be glad to hear from you in that venue, too. And, you know, I think that that's a good point for us moving forward too, to think about maintaining a cultivation of the commitment to hearing from our stakeholders in the public.

And Christine, I'm interested to hear some of your reflections as well and your thoughts about what you may pass on for us to think about in the future.

CHAIRPERSON GOERTZ: Thank you. Nakela. As is frequently the case, if I -- after Sharon speaks, I have very little new to add and she has said it far more eloquently than I ever could, but I still want to take this opportunity to make a few remarks and perhaps even reiterate some of the things that both her and Bob have said.

It is been the honor of my professional
life to be on this PCORI Board and to serve as the
Chairperson. And when Nakela asked us to consider
some of our fondest moments. Well, the first thing
that popped in my mind is the day that she decided
to become our Executive Director. That is
definitely up there.

But there are literally thousands of those
memories and moments and it's like trying to choose
who your favorite child is.

But when I think about landmarks like
getting reauthorized and bringing Nakela on board
and some of the decisions that the Board has made.
I think those have been incredibly important. But
my fondest memories are all about the relationships
and the opportunity that I've had to get to know all
the PCORI staff and the Board members, all of you
that are on the Board now, and those of you who came
before this time and left. I just treasure those
moments.

And in addition, when I think about the
ways that PCORI has changed me, and it has in
profound ways, much of that change is the way that
my worldview was altered by meeting with our stakeholder groups. And so if I have -- and we did that early on in our development, we actually traveled around the country and as a Board met with stakeholder groups and the advice that I would have to you as a board is to find a way to resurrect some of those direct connections with stakeholders, because I truly believe not only will it change you, but it will change the direction of PCORI to have that direct contact in the way that I believe it did in our early years.

It helps to keep you focused always on why we're here.

And I think that's one of the reasons why we were able to so effectively leave our stakeholder hats at the door and come together in the way that we did as a board because we had this constant reminder that this was not about us. This was real, not even so much about a particular stakeholder group, but really about patients and the whole collective wisdom of all of the stakeholder groups.

And I think about what I'm most proud of.

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Again, there are countless options to choose from and certainly the platform that we've built in order for the next iteration of PCORI to launch from is something that I'm particularly proud of. But the thing that I'm most proud of is that I truly believe that PCORI has changed the conversation, the national conversation when it comes to patient-centeredness. It's put patient-centeredness on the map in a way that really matters, that's really impactful.

I see CMMI now talking about being patient-centered and, you know, the DOD and the VA and NIH. I was not hearing any of that and I would've noticed before PCORI began its work. So I'm proud that we have helped to facilitate in a profoundly meaningful way that national conversation and that it is now becoming more and more, not only accepted, but expected for researchers, regardless of who your funding source is to take a patient-centered perspective and to put together multi-stakeholder teams. And, again, I think PCORI deserves a lot of credit for bringing that happen, making that happen.
My hope is that you now take the platform that has been built and you use that to do something that is extraordinary, that is bold and impactful. My day job is primarily focused on conducting research, comparative effectiveness research, and implementing the data that we already know in pursuit of doing a better job of caring for people with low back pain. Low back pain is the number one spend in direct costs in the healthcare delivery system, largely for treatments which largely don't work and can often cause much more harm than benefit to patients.

My hope is that you, that PCORI takes on those really difficult tasks, those really difficult issues, like low back pain to the extent that 12 years from now when those Board members who are coming on this week are graduating, that what they'll be able to say is their greatest accomplishment is not only that they set up the framework and that they built the platform, but that the entire healthcare system is profoundly changed because of the work that PCORI has done.
My advice to new Board members is, as Sharon said, the GAO has done an outstanding job of appointing new Board members just consistently across the board, and I have no doubt that they will do, have done that same excellent job this time. And over the past years as new Board members have come on board, and especially in the last three years as I've been Chair, I've sometimes had new Board members say, well, I was going to bring that up during the meeting, but I didn't know if I should. And what I'll never forget driving to my very first PCORI Board meeting, pretty much frightened to death because thinking about all of the Board members, you know, the Director of NIH and the Director of AHRQ, and people like Harlan Krumholz who makes the stock market drop if he says something negative, and thinking, what do I have to contribute?

And what I learned really at that very first meeting is that all of us have something to contribute, and we have been put on this board because we do have a voice. And so, my advice to
new Board members would be to use that voice. It is incredibly, from the very beginning, as Sharon said, it's incredibly important that that happens, so that PCORI can be the best organization it can possibly be. And if you do use your voice, I guarantee you that PCORI will listen. Thank you.

[Applause.]

DR. COOK: Well, thank you for the collective wisdom, even just now, in terms of thinking about the path forward and for everything that you've done for us over the years, there's no way to thank you for your service of the past 12 years. It just simply exceeds anything that we can say or do.

But I hope you know that you will always be in the hearts of PCORI and we hope that you'll carry PCORI in your hearts moving forward.

And to that, we celebrate our fond farewell for the four of you and your service on the Board.

CHAIRPERSON GOERTZ: Thank you.

DR. COOK: Thank you.

[Applause.]
CHAIRPERSON GOERTZ: So now, for the final time, let me close by thanking those of you who joined us today. Our meeting agenda approved minutes from the July 26, 2022 meeting. The slides and the archived webinar will be posted to PCORI’s website within a week.

As always, we recommend -- we welcome your feedback. We recommend your feedback; we beg you for your feedback --

[Laughter.]

CHAIRPERSON GOERTZ: -- at info@PCORI.org or through our website at www.PCORI.org. Thank you again for joining us. Have a good afternoon.

[Whereupon, at 12:05 p.m. EST, the Patient-Centered Outcomes Research Institute’s Board of Governors meeting was adjourned.]