PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

11:30 a.m. EST
Thursday, December 2, 2021

Webinar

[Transcribed from the PCORI webinar.]

B&B REPORTERS
29999 W. Barrier Reef Boulevard
Lewes, DE 19958
[302] 947-9541
APPEARANCES:

BOARD OF GOVERNORS

Kara Ayers, PhD
Kate Berry
Jennifer DeVoe, MD, MPhil, MCR, DPhil, FAAFP
Alicia Fernandez, MD
Christine Goertz, DC, PhD [Chairperson]
Michael Herndon, DO
Russell Howerton, MD
Connie Hwang, MD, PhD
Sharon Levine, MD [Vice Chairperson]
Karin Rhodes, MD, AHRQ Director Designee
James Schuster, MD, MBA
Kathleen Troeger, MPH
Danny van Leeuwen, MPH, RN
Robert Zwolak, MD, PhD
AGENDA

Welcome, Call to Order

Christine Goertz, DC, PhD, Chairperson

Roll Call

Consider for Approval:
Minutes of the October 26, 2021 Board Meeting

Nomination of Advisory Panel on Clinical Trials (CTAP) Member

VOTE

Executive Director’s Report:

Nakela L. Cook, MD, MPH, Executive Director

Year in Review

Consider for Approval:
FY2022 to FY2024 Commitment Plan

VOTE

Proposed Research Agenda for Posting for Public Comment

VOTE

Break

Consider for Approval: Research Award Slates Cycle 1 2021 Pragmatic Clinical Studies (PCS)

B&B REPORTERS
29999 W. Barrier Reef Boulevard
Lewes, DE 19958
[302] 947-9541
AGENDA [CONTINUED]

Consider for Approval:
Research Award Slates [CONTINUED]
Cycle 1 2021 Pragmatic Clinical Studies (PCS) 107

Jennifer DeVoe, MD, MPhil, MCR, DPhil, FAAFP, Selection Committee 115

Carly Khan, PhD, MPH, RN, Associate Director, Healthcare Delivery & Disparities Research, HDDR 116

VOTE 118

Consider for Approval: Research Award Slates Broad PFA 119

Steve Clauser, PhD, MPA, Program Director, HDDR 120

Holly Ramsawh, PhD, Senior Program Officer, Clinical Effectiveness and Decision Science (CEDS) 121

VOTE 122

PCORnet Coordinating Center 124

Laura Lyman Rodriguez, PhD, Interim Chief Program Support Officer and Senior Advisor to the Executive Director 124

VOTE 128

Consider for Approval:
Cycle 1 2022 Targeted PFAs 130

Nakela Cook, MD, MPH, Executive Director 130
AGENDA [CONTINUED]

Consider for Approval: [CONTINUED]

Cycle 1 2022 Targeted PFAs  
Brief Interventions for Adolescent Alcohol Use

Alicia Fernandez, MD, Chair, Science Oversight Committee

Els Houtsmuller, PhD, Associate Director, HDDR

VOTE

Prevention, Early Identification and Treatment of Delirium

Yewande Akinbami, MD, MPH, Program Officer, CEDS

VOTE

Consider for Approval:
Health Systems Implementation Initiative (HSII)

Michael Herndon, DO, Chair, Engagement, Dissemination, and Implementation Committee (EDIC)

Joanna Siegel, ScD, Program Director, Dissemination and Implementation (D&I)

VOTE

Public Comment
Kristin Carman, MA, PhD, Director, Public & Patient Engagement

Wrap up and Adjourn

Nakela L. Cook, MD, MPH

Christine Goertz, DC, PhD, Chairperson

B&B REPORTERS
29999 W. Barrier Reef Boulevard
Lewes, DE 19958
[302] 947-9541
CHAIRPERSON GOERTZ: Thank you so much.

Good morning and welcome to the December 2, 2021 meeting of the PCORI Board of Governors. I’m Christine Goertz, Chairperson. I want to welcome all of those of you who are joining us for today’s Board meeting via teleconference and webinar. Thank you to everyone who has joined us virtually online and on the phone. We're very pleased to have you with us today.

I want to remind everyone that conflict of interest disclosures of Board members are publicly available on PCORI’s website and are required to be updated annually, or if the information changes.

You've recently been sent an email asking you to complete your annual updated conflict of interest disclosures, if you've not already done so, please do so before January 29, 2022. Board members are also reminded to update your conflict-of-interest disclosures when the information changes.

If the Board will deliberate or take action
on a matter that represents a conflict of interest for you, please recuse yourself or inform me if you have any questions.

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

All materials presented to the Board today for consideration today will be available during the webinar. The meeting is being recorded and an archived webinar will be posted within a week.

Rachel, would you please call roll?

DR. AYERS: Present.
MS. BARNES: Kate Berry.
MS. BERRY: Present.
MS. BARNES: Tanisha Carino.
[No response.]
MS. BARNES: Francis Collins or Michael Lauer, Designee of the NIH Director.
[No response.]
MS. BARNES: Jennifer DeVoe.
DR. DeVOE: Present.
MS. BARNES: Alicia Fernandez.

DR. FERNANDEZ: Present.

MS. BARNES: Christopher Friese.

[No response.]

MS. BARNES: Christine Goertz.

CHAIRPERSON GOERTZ: Present.

MS. BARNES: Mike Herndon.

DR. HERNDON: Present.

MS. BARNES: Russell Howerton.

DR. HOWERTON: Present.

MS. BARNES: James Huffman.

MR. HUFFMAN: Present.

MS. BARNES: Connie Hwang.

DR. HWANG: Present.

MS. BARNES: Sharon Levine.

DR. LEVINE: Present.

MS. BARNES: Michelle McMurry-Heath.

[No response.]

MS. BARNES: Barbara McNeil.

[No response.]

MS. BARNES: David Meyers or Karin Rhodes, Designee of the AHRQ Director.
DR. RHODES: Karin Rhodes is here.

MS. BARNES: Eboni Price-Haywood.

[No response.]

MS. BARNES: James Schuster.

DR. SCHUSTER: Present.

MS. BARNES: Ellen Sigal.

[No response.]

MS. BARNES: Kathleen Troeger.

MS. TROEGER: Present.

MS. BARNES: Daniel van Leeuwen.

MR. VAN LEEUWEN: Present.

MS. BARNES: Janet Woodcock.

[No response.]

MS. BARNES: Robert Zwolak.

[No response.]

MS. THOMAS: Dr. Goertz we have a quorum.

CHAIRPERSON GOERTZ: Thank you so much.

Can we have the next slide please?

As you can see from this side, we have a very full agenda today. We're starting out with our Consent Agenda and then we'll have the Executive Director’s report, which is really a review of our
annual review at the end of the year.

And then we have a lot of work in front of us. We will be considering for approval our FY 2022 to 2024 Commitment Plan, the proposed agenda -- our proposed research agenda that we hope to post for public comment, a number of award slates, Targeted PFAs, and a health systems implementation initiative followed by our public comment period.

Just a reminder to please keep us informed about your attendance at the meeting today, because we have a number of voice votes and want to keep close track.

In addition, we have an unusual large number of Board members who are either not able to join us today or are only able to join us for a portion of the meeting. So we need to make sure that we've got a quorum at all times.

We're going to start out with that Consent Agenda and next slide please.

Okay. The two items on the Consent Agenda then are the meetings from our October 26th, 2021 Board meeting, and also the nomination of Cristina
Murray-Krezan as a member of the Advisory Panel on Clinical Trials to serve a three-year term. So starting now and through August of 2024, or until a successor is appointed because this is a replacement appointment. She has been recommended for Board approval by the Methodology Committee. Her stakeholder group is that of a researcher, she's a statistician, and she is at the University of Pittsburgh.

Next slide please.

So I would like them to call for a motion to approve our Consent Agenda for today.

MS. TROEGER: Troeger, with a motion to approve.

DR. LEVINE: Sharon Levine, second.

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

[No response.]

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

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?
[No response.]

CHAIRPERSON GOERTZ: Abstentions?
[No response.]

CHAIRPERSON GOERTZ: Okay. Thank you.

Now, before we get started, I'd wanted to I wanted to just take a moment to thank Andrew Hu for his service. As many of you know him, he has been with us for the past six years as our Director of Public Policy and Government Relations.

He let us know recently that he will be leaving us this month to pursue another opportunity, as Andrew was a key person involved in our reauthorization process, he helped to build our Public Policy and Government Relations Program to the very effective entity that it is today. He is responsible for helping reinvigorate our relationships on the Hill, as well as engage at a higher level with the broader public policy community.

And he has -- that those efforts really were instrumental in helping to demonstrate to Congress the value of -- that PCORI brings to our
nation, leading to our 10-year reauthorization. So we owe a great debt of gratitude to Andrew and Andrew do you mind putting your camera on for a second?

MR. HU: Okay.
CHAIRPERSON GOERTZ: Thank you. Thank you so much for your service to the PCORI. And I know that the entire Board joins me in wishing -- thanking you for everything that you've done and wishing you every success with your future endeavors.

MR. HU: Great. Thanks Christine. Thanks everybody on the Board. I mean, it's been a great ride and I've enjoyed every moment of it and I couldn't have done it without the support of the team and all -- obviously all of you also. I definitely appreciate it and I'll definitely be watching and supporting PCORI just from a different, different perspective now, but I look forward to what's coming next for the organization.

CHAIRPERSON GOERTZ: I absolutely look forward to staying in touch. Thanks again. Thank

B&B REPORTERS
29999 W. Barrier Reef Boulevard
Lewes, DE 19958
[302] 947-9541
you so much. Take care.

    MS. HU: Bye.

    CHAIRPERSON GOERTZ: Bye-bye.

    All right, Nakela. I'm going to turn it over to you to get for our year-end review.

    DR. COOK: Thanks Christine. And it's good to see everyone this afternoon and well almost afternoon on the East Coast, and I'm pleased to give you my report today to both review our end-of-year Dashboard, as well as kind of some highlights of the year that we've just are wrapping up.

    Let's go to our next slide.

    So we'll kick it off with our fiscal year 2021 Dashboard review. And here you see the snapshot of our Dashboard with several of those quantitative measures that really lend themselves well to encapsulated reporting and they're represented here with increasing measures of impact. If you look along the left of the slide here, you'll see inputs from, or you'll see measures from inputs increasing toward use and as you progress down this slide.
And the Dashboard, actually something that continues to evolve. And from this focus that was primarily on inputs in our early days to process. And now our progress on our goals, our output and uptake. And we're looking ahead to our measurements of impacts as we continue to move forward with our Strategic Plan and subsequently evolve our Dashboard to those priorities.

So as you see across the top row here, those are our input and process metrics and include things like our funds committed, our research project performance by quarter against the target. And there are things on this Dashboard that are color coded as green, yellow, or red to indicate if we're on track.

Our second row has several of those process and output metrics, including our final research reports, as well as the posting of results to PCORI's website and results that are published in the literature.

And then finally at the bottom of the slide, you can see uptake in use metrics on that
last row. And we have things there such as uptake into patient and public resources, uptake of results into a clinical decision tool called UptoDate, as well as other examples of uptake.

And so at a glance, just from the color coding, you can see that we are meeting all of our targets on these metrics and related to our funds committed. We're going to talk about that more when we focus in on the Commitment Plan discussion in our next agenda item, but you can see here that we met our ambitious target of $482 million of commitments in fiscal year 2021.

What I'm going to go through in the following slides, a lot of details on a lot of the metrics you see here on this snapshot. So I won't spend a lot of time on them, but I did want to just mention that two of them that we won't spend as much time on are the Time to Release of Research Findings. And you can go back a slide for just a moment.

And you can see here that 100 percent are within the 90-day limit. And that's something
that's really important from our authorizing legislation. And our average in terms of our time to release of research findings is about 86 days.

We also have on this slide, an Uptake into Patient and Public Resources, which is a relatively new metric and one that we're continuing to evolve. And this is where we've tried to develop a way where we can track citations that mentions the results from PCORI-funded studies and to things like patient and public facing resources, such as Wikipedia or health blogs, WebMD, or even the Mayo Clinic reports and other websites. And so, we're going to be expanding this metric over time. And this is an area we may continue to ask your input on what would be valuable to track.

We can go ahead to our next slide.

So here, I wanted to spend a little bit of time on the status of PCORI-funded research projects. And here you can see the percentage of projects that are on track in the green or yellow zones, and those that are off-track in the red. And the last 12 quarters are reported here. And
overall, for the most part, PCORI-funded projects are on track and our green color-coded ones are those that are highly to meet the objectives as planned. And you can see that 60 percent of our projects fall in this range, with a slightly lower number in the last quarter here as compared to prior quarters, and more that have kind of shifted into that yellow zone, which we think is related to some of our COVID-19 implications on our portfolio.

So the yellow zone is basically those projects that may not be able to meet objectives within the project period. And they're 31 percent of our projects are falling there and you see that slight uptick in the yellow zone toward the last quarter here.

And in the orange. These are the ones that will not meet objectives within the project period. You see nine percent there.

And red, those that just cannot meet original objectives and that's less than one percent.

So at the end of the fiscal year, 2021, we
had 34 active research projects that had started and were not yet eligible for assessment. So they're not included here, but we do measure and assess status on a quarterly basis based on milestones, recruitment, and the assessment of our program officers in terms of progress toward goals.

Let's go to the next slide.

So I did want to take just a moment to talk about some of those COVID-19 disruptions and delays in our research portfolio and our funded research portfolio. Because as I showed on the prior slide you can see that the status evaluation of PCORI-funded studies are on the left here. And so, a little bit of a summary of what you saw on the prior slide. And what we're learning is that about 88 percent of projects in the yellow, orange, or red zones have COVID-19 related delays.

And mostly they're partly due to COVID-19, about 60 percent or so of that subset or primarily due to COVID-19. And that's about 40 percent of that subset.

We also know that through our evaluation,
that the most common cause of a delay is a significant decrease in recruitment in other study activities. And that's about three quarters of those that fall into that zone.

And our staff have really been working closely with authorities to ensure that these projects receive the necessary contract modifications to make sure they can successfully complete projects. At this time, we're still learning. So we don't have a lot more to go into depth here. Other than to allow you to understand that the kinds of modifications that are occurring are mostly related to things like extensions or modifying a protocol, approach, or intervention in order to deal with either remotely trying to assess things or thinking about other routes to assess outcomes due to some of the disruptions.

We also think that many might be either significantly altered, delayed, and we think very few in the termination realm. I would also just mention that, you know, some interesting literature starting to emerge as well around COVID-19’s effect

B&B REPORTERS
29999 W. Barrier Reef Boulevard
Lewes, DE 19958
[302] 947-9541
on the research enterprise in general. And this is
generally what we're seeing across other funders as
well. But we certainly have also seen a decrease in
researcher productivity during the pandemic and as
well as increased stress on mental health for
researchers, and a differential effect on women and
parents of young children and people of color, and
that are really affected by pandemic-related
disruptions and need more support.

So we're really attuned to those issues and
are working very hard with our awardees to make sure
we're addressing things through modifications of
awards that's appropriate.

Let's go to the next slide.

So PCORnet also has metrics that are
tracked on our Dashboard and has been a source of
ongoing contributions to a lot of the COVID-19 work
that's been funded by the PCORI and others. And
while you don't see PCORnet on the overall snapshot
Dashboard, it has its own metrics and issues that
are raised to the Board as appropriate. And we now
have the PCORnet Dashboard available on PCORI's
website for full transparency. And you can see that it includes about 13 metrics monitoring things like Front Door requests, COVID-19 projects, data quality, publications, and resource utilization, and funded studies.

And the PCORI staff present these metrics to the Research Transformation Committee for Oversight and closely monitor progress as well on the prioritizing principles for infrastructure that are related to PCORnet and expect to see as well as significant increase in Phase 3 and the research throughput, both by the network partners, as well as by the enhanced Front Door, which is really a subsequent move from the discussions that were had in the PCORnet priorities work through.

So Phase 3 of the PCORnet program is also going to have infrastructure milestones that will be set requirements for our clinical research network leadership and participation, as well as engagement of their patient partners and large PCORnet studies of national scope. So we'll look forward to some of those activities on the Dashboard in the future.
You can go to the next slide.

So this slide just tries to show a little bit of detail on some of the metrics that are focused on outputs. And here, you'll see the data related to the posting of final research report on PCORI-funded studies on our website, and we've made a lot of CER results available to the public. And here you can see the total number of final research reports posted by year for a total of about 328 at the end of September.

The final research report really is this comprehensive peer-reviewed report on a PCORI-funded study. And it typically can be the equivalent of the length of about three-to-five journal articles, given the depth of information that's provided and these reports have been posted on time for the most part. And from our policy, we talk about the importance of having the publicly available results on our website no later than 12 months after the final research report is accepted.

There's also a lot of data on attention to our results pages. And what we found is that...
downloads of final research report average about 1,500 per quarter last year, and for research results pages we find that there are a lot of unique visitors to our research results pages. And this can average somewhere like 19,000 to 20,000 per quarter last year. So this is a really, I think, robust resource for the public to find information about the PCORI's funded studies.

Let's go to the next slide.

So I did want to talk a little bit about attention and the attention that this studies from the PCORI-funded portfolio actually receive. And the results that are being posted on our website are not just results of what we funded, but they're actually very noteworthy and are garnering attention. So PCORI-funded investigators derived multiple publications per funded project with over 3,000 publications resulting from PCORI-funded studies thus far and of these over 2,000 are with empirical results. And about 400 of these are primary or secondary CER results.

So here we see the attention to these
results publications as measured by Altmetric scores. And so, on the left side you see that a lot of our publications from PCORI-funded studies have high Altmetric scores, greater than 20, but on the right, you can see that on average 13 percent of CER results publications exceeded the target of greater than 10 percent of results publications garnering the top 10 percent attention in the relative journal.

I'm going to drill a little bit more on Altmetric scores. We can go the next slide.

And this slide just gives you an example of highlights of attention to six PCORI CER results, publications as measured by Altmetric scores of greater than a hundred. These are really high scoring CER results publications from fiscal year 2021. And the score indicates attention in news articles or on social media blogs and in other types of blogs.

And so of note, you'll see the first study here is one that compared antibiotics with appendectomy for appendicitis and is of the top 11
percent for an Altmetric score for articles that were published in the New England Journal of Medicine.

The second one here is a study of the Comparative Effectiveness of Aspirin Dosing and Cardiovascular Disease, or what we know as the ADAPTABLE study, which was conducted within the PCORnet. And you can see here that it had at the top 18 percent for an Altmetric score for articles published in the New England Journal.

And the third one is around an “Association Between Gender-Affirming Surgeries and Mental Health Outcomes,” and is among the top three percent of attention in JAMA Surgery.

And further down, you can actually see a study that was funded as a COVID-19 enhancement project, examining “Metformin and the risk of mortality in patients hospitalized with COVID-19: a retrospective observational analysis.” And this was in the top five percent for the journal.

So these are just from fiscal year 2021, but you can see here that journals like the New
England Journal of Medicine and JAMA tend to have higher Altmetric scores. And this is just a snapshot of some of those higher attention-grabbing studies that have been published from the PCORI-funded studies.

We can go ahead to the next slide.

So I wanted to give you another example that relates to increasing information for health decision-making. And this is hot off the press. This is the Regain trial that was published in October of 2021. And these are results from a PCORI-funded study that found that spinal anesthesia and general anesthesia are equally safe for hip fracture surgery. And we know that hip fracture surgery is that a large issue in the United States with about 300,000 adults or more in the US that break a hip and almost all occurring in those that are 50 or older, and that's on a yearly basis.

And nearly all of these individuals are going to need surgery with anesthesia. So this study actually compared how general anesthesia versus spinal anesthesia affected recovery and long-
term health in about 1,600 patients that were over
the age of 50 and scheduled to have surgery for hip
fracture, and found that really spinal anesthesia
for hip fracture surgery in older adults was not
superior to general anesthesia with respect to
survival, as well as the ability to walk two months
after surgery. And both forms of anesthesia were
equally safe.

So these results are the kinds of results
that could help decision-making about which
anesthesia option fits best a patient's preference.
This is one of our large pragmatic clinical studies
that we funded at about $12 million. It was awarded
in 2015, and that was actually the first year that
the pragmatic clinical studies PCORI funding
announcement was released. And you can see on the
right here are the high Altmetric scores for this
publication and the top 10 -- top five percent for
those scores within the publications in the New

Let's go to our next slide.

So continuing on that trend of really our
outputs and I wanted to take a look here with you at the public availability of our primary CER results. And as you can see here as of Quarter 4 of 2021, 388 PCORI-funded studies have primary CER results, peer-reviewed and publicly available. And this number had been steadily increasing and continues to increase.

And this includes the publication of both primary and second — oh, well, if you include the publication of secondary CER results, it actually goes up from 388 to 416 that are available in the public domain. Let’s go to the next slide.

I really love the slides that I’m going to show you. Next slide. And this talks about how the research results from PCORI-funded trials are published and how it’s really been important that we take on a specific process at PCORI to get results out to the public sooner.

So this slide actually demonstrates the percentage of CER results that are available by publication relative to the primary completion date of the clinical trial. From what you can see here
is that the research results from PCORI-funded
studies and the blue dashed line published in the
peer-reviewed literature at a similar rate, or
really better even than the benchmark, which is in
the orange line. Let's look at the next slide.

So this might actually add then what you
see here as a purple line, as the percentage of CER
results from PCORI-funded research studies that are
publicly available by publication or by posted
abstract relative to the primary completion date of
the trial.

And so, one of the first things you'll
notice here is how remarkably the curve has bent
back into the left with earlier posting of results
relative to the benchmark. And when we look at this
against our target of having a hundred percent of
CER results publicly available at 24 months, we're
moving closer and closer to that ambitious goal. We
have 82 percent at 24 months and a hundred percent
at 36 months. Next slide.

And so, I finally want to bring it all
together and here you can see the difference that
the PCORI peer review and posting of abstracts makes. PCORI's process provides complete and earlier availability to the public of research results from PCORI-funded CER studies over and above the publications alone. And PCORI-funded investigators are not hampered in publishing by going through this peer review process, the blue and orange curves are really similar as you can see here, and then they depart.

So we really set this ambitious target of bending back this curve and we're making progress. And I just wanted you to see this and this lovely depiction. Let's go to the next slide.

So I just want to shift gears and focus a little bit on uptake measures of results from PCORI-funded studies on the path to implementation. And so, here you see uptake in evidence-based clinical recommendations and we'll start with UpToDate, one of those clinical decision tools, and you can see our provisional target based on historical data is to have about 28 results taken up into UpToDate per year. And at the end of the year, there were 32
citations of CER results in UpToDate and 98 that are cumulative to date, and you can also see citations and other clinical recommendations with 20 this year, this fiscal year and the cumulative of 74 to date.

And there are other examples of uptake on the right side of the slide, in addition to tracking uptake in UpToDate, we also track other examples of uptake to things like systematic reviews, guidelines, or policy documents, and other notable examples. And the provisional target is really based on historical data and it's to have about 48 examples of uptake per quarter and 190 or so by the end of the year, and generally to see some positive trends in our uptake of CER results.

And here you can see those targets were met. So let's go to the next slide.

This light just provides you an example of our goal of trying to speed uptake and use of information. And here you can see that the results from a PCORI-funded Patient-Powered Research Network research demonstration project were taken up into
two UpToDate clinical topic pages.

The results were cited from a study on the comparative effectiveness of specific Carbohydrate and Mediterranean Diets to induce remission in patients with Crohn's disease. And you can see the quotes here that there was no significant difference in rates of symptomatic remission after six weeks of adhering to this diet compared with the Mediterranean diet. And thus, there is no good evidence, as it's concluded in UpToDate, for specific dietary regiments, other than to eat a healthy, diverse diet.

And this is based on the results from a PCORI-funded study. Let's go to the next slide.

So I just briefly wanted to land here on the snapshot of the Dashboard again for you to take one final look as we move into our discussions.

Let's go to the next slide.

So I just wanted to pause here and invite some discussion on the Dashboard before I come back and tell you a little bit more about highlights from the year in review.
So we're really interested in hearing whether our fiscal year 2021 Dashboard and a lot of the background materials cover the topics that are most important for you to review and whether or not you have questions or comments about performance on any of these Dashboard indicators. And as we move forward in developing our Strategic Plan, it'd be really helpful to hear the role and content you envision for the Dashboard in measuring progress and measuring success, because this actually can be a component of us in terms of our thinking about our Strategic Plan is how we want to evaluate it moving forward and how we leverage this Dashboard to help us do that.

So, Christine I thought we could pause here for some questions and then before I move forward, would you like to facilitate any discussion?

CHAIRPERSON GOERTZ: Absolutely. And I see Mike, if you want to get us started.

DR. HERNDON: You bet. Thank you, Nakela.

How do we use the Altmetric scores and the information gained from these Dashboards about the
utility of our studies to drive our topics for study selection.

DR. COOK: That's a great comment. And I think you may even be thinking about the research results and how research results really help us in thinking about what we do next.

DR. HERNDON: Exactly, yes.

DR. COOK: We're in a really unique position, I think, where we're starting to see a lot of research results coming to fruition. And so, it's the perfect timing for us to think about that, Mike, and I appreciate the comment.

We do -- and I know I'm Joanna Siegel's on the line. We do go over the output of our research studies on a regular basis, both through the peer review process, as well as just a research results review. Both for identifying studies that may be right to consider for implementation awards, but also to understand where we are in the kind of evidence-base and different areas that we've pursued thus far.

And so, it's probably not as formal as
processes you may be describing, but it is part of what we do take into account in terms of how we digest where we've been and think about what we could be doing in our next steps. And those are some robust discussions that happen PCORI-wide on a regular basis.

DR. HERNDON: Thank you.

CHAIRPERSON GOERTZ: Thank you. Danny.

MR. VAN LEEUWEN: Yes, thanks for this report Nakela. I want to make several comments. The first one is this what we mean by a public available data -- or results. And the first is I think when you say public you mean research industry because most of what you've shared in terms of the Dashboard. And so, for those that are research industry you know, so peer-reviewed journals and the like, I'm wondering about the pay wall. And you know, what is all of these really public and that term?

I also think that, like, when I think about public, I think about non-research industry available material and about PCORI and its results.
And I think it's not just about the study results, but it's about PCORI itself about strategy, about equity, about community and patient engagement, about our priorities. And I'm wondering how we are orienting ourselves and measuring the sort of the non-research industry and the non-results part of what we do, which is really considerable and which the public might actually have considerable interest in.

DR. COOK: Yeah. Maybe just a couple of comments there, Danny. So everything I presented also was included in our lay abstract reports and on our website to all audiences. So we do try to make sure that we're including results for the public in a way that could be understood at different for different stakeholders at different levels.

So everything is translated into lay abstracts on our website, but we also have started to look for our ability to have uptake in different venues. And some of that actually came from, I think, a comment you made earlier when we reviewed the Dashboard maybe at mid-year or last December,
where we started to then track to see the uptake and how our results are getting uptake and into some of the more lay-friendly venues. And I mentioned blogs and other types of sources that were looking at now. The last thing that I did want to say, though, is I liked your comment about beyond the research results and how we track our effectiveness around other types of activities that PCORI is engaged in. And we can think about that a little bit more together in terms of how that may be possible. We do try to make sure that we have that information available on our website, but tracking the effectiveness of it, in many ways I'm not as sure that we've figured out ways to do that.

MR. VAN LEEUWEN: Yeah. And I think the part of the uptake is that other people -- so it's not just you know, maybe people get directed to the PCORI website, which is rich, but that is not necessarily the original place or the first place that people would go. And so, it's the encouraging. So like in my work as a podcaster, I try to, you know, highlight what's happening with PCORI
and then refer back to the website. And I'm just wondering how we can encourage other people who are more and more interested in what PCORI is doing, especially in community and patient engagement.

The other thing I wanted to just say is that I found the PCORnet Dashboard really difficult in the sense that I didn't know, like what it's -- it didn't speak to me, like, was this good? Was this where we wanted to go? You know, it didn't really -- I didn't know what to make of it.

And so, I am really looking forward to our doing the, you know, the national priorities and our strategy and building a Dashboard that relates to that. And it makes me think that we need to get comfortable with our Dashboard, having a lot more red and yellow, because if it's all green or mostly green, I don't feel like we're really stretching.

And, you know, that's what our goal is to -- is to lead the industry in what we're good at. And so, that means that it's going to take us a while to get there. And so, I look forward to you know a shift of our Dashboard that shows our reach.
and our struggle.

DR. COOK: Yeah, I think one of the things that strikes me on your comment is we may be seeing that evolution occurring, where our Dashboard really tracked with our original Strategic Plan. And now as we shift with where we're going with our strategic priorities and we're moving to our next phase, we'll see that shift with our evaluation and Dashboard. And I understand it used to have a lot more yellow and that you're probably seeing the results of years of effort.

CHAIRPERSON GOERTZ: Well, thank you, Danny, for those comments and Nakela for that response. And I have thought similar to Danny. I think that -- and I'm wondering actually Sharon, if it would be reasonable to ask our Strategic Planning Committee to look at the idea of what benchmarks might be appropriate for us to consider as we're looking into our next phase.

And in fact, as we're starting to develop more and more of these ad hoc committees, like our PCORnet Committee, for instance, is it possible to
have those groups start to think about what sort of things should end up on our Dashboard relative to the work that the group is -- that the work that the group is doing and perhaps to make some recommendations to the Board about what benchmarks we may want to consider in those particular areas.

And just before I turn it over to Sharon, just really quickly to -- I did have a question.

Do we, again based on Danny's comments about recognizing who our audiences are that we have a wider stakeholder audience than scientists and scientific journals. Do we look at to what extent Google searches are leading people to the content on our website? Is there a way to track that more closely.

DR. COOK: Christine, were you thinking kind of looking at utilization -- like utilization metrics and things like that on our PCORI website?

CHAIRPERSON GOERTZ: Mm-hmm.

DR. COOK: Yes. And actually it's in my next presentation, I was going to give a little update about the fact that our website has actually...
been revamped on a new platform that's going to allow us even to do some of those measures and metrics in terms of traffic to the site, even more robustly. So this is something that our communications team does track and we'll be able to continue to track moving forward.

CHAIRPERSON GOERTZ: And now with our new website, related to that, will it be possible to optimize the -- our web presence so that if somebody Googles a particular topic area, for instance, that it may prioritize the information on our website?

DR. COOK: I would be hesitant to answer that one, given my lack of expertise. Tasha, are you on the line? Our director of communications --

CHAIRPERSON GOERTZ: We don't -- we don't need to go down that, that path right now, but it's just, those are the kinds of things I think we need to be thinking about as we move forward.

And now I wanted to go to Sharon. What are your thoughts about asking the Strategic Planning Committee to start thinking about how we might -- what we might want to add to our Dashboard?
DR. LEVINE: I think there are two parts to it. One is, do we -- or how do we reorganize the Dashboard so that whatever metrics we choose to follow, and I suspect they will evolve and change over time, fit clearly -- have line of sight with the strategic priorities that we've established with the national priorities and with the research agenda.

So the first stage of this, I think, is thinking about looking at the current because the current Dashboard was in many ways built from the ground up from specific, it was -- we picked specific metrics and said this would be worth watching, you know, based on either stakeholder input or Board member interest in tracking certain things.

And I think we're at a point now with the national priorities and soon with the research agenda to say, okay, let's start with the bigger picture of what our priorities are and then ensure that the metrics we're tracking enable us to follow our progress toward achieving national priorities.
through funding research that fits with and is
aligned with the national priorities.

And I think that's certainly a conversation
we can begin at the Strategic Planning Committee and
ultimately it is the Board’s -- a conversation for
the entire Board to have.

CHAIRPERSON GOERTZ: Yeah. Thank you
Sharon. That's helpful.

Well, Nakela, I think we're going to turn
that back over to you. You have a lot of material
to cover in a short period of time.

DR. COOK: Yes.

CHAIRPERSON GOERTZ: So we'll let you get
started with that.

DR. COOK: Okay. And I'll shorten, but I
may go just a few minutes long here. Let's go to
the next slide.

And I wanted to just begin a part of this
discussion that's called a Year in Review. Just to
give you some highlights of what's happened over the
course of 2021 and it's really been a remarkable
year. It’s hard to believe we're already preparing
to close out another calendar year.

And so, we'll start with some of those memorable moments and then we'll get to some of the accomplishments of the organization, the Board, over the past year.

So one of our most exciting moments was the welcoming of new staff at PCORI and among the number of remarkable individuals that have joined the PCORI over the year. We have also three new leaders at PCORI and we welcome Sri Mishra in August of 2021 as our inaugural Chief Information Officer, and Yolanda Hutchins in September of this year as the PCORI's Chief People Officer.

And in just a few weeks, we'll also be welcoming Dr. Carolyn Best. Who will be joining the PCORI as our new Program Operations Chief, and she'll join us from the American Neurological Association where she served as the Director of Research there.

Let's go to our next slide.

So I just also wanted to highlight for our Board members that earlier this month PCORI launched
a new and redesigned website, and we were just
making reference to that in our last conversation.
And you'll immediately notice that the updated
website has a different look and feel, but the
website has also undergone more than just a cosmetic
make-over and the website's been moved on to a new
platform with a robust and sustainable technology
foundation and has improved infrastructure.

So it's going to lay the groundwork for us
to have a lot of different new features and content
and robust opportunities for analytics, as we just
talked about.

You'll see that we have expanded our
Explorer portfolio tool, have some new filters and
things of that nature. Our PCORI funding
announcement section will look different and we've
added a PCORI news hub and a one-stop resource to
learn about what's happening at the PCORI.

So if you haven't visited the new website,
please take a moment to do so and peruse all the
improvements. I think that it's going to be a
really important tool for our stakeholders to better
access all the critical information that they're looking for. Let's go to our next slide.

I'm also really delighted to announce that this year PCORI was awarded a MarCom Gold Award for our 2020 Annual Report. And this is the third consecutive year that PCORI's been recognized for our annual report. So the MarCom Awards are a program of awards that are international in scope. It's a creative competition that recognizes outstanding achievements by marketing and communications professionals. And while it's administered by the Association of Marketing Communication Professionals, it really takes entries, and over 6,000 entries came in this year from corporate marketing and communications departments, advertising agencies, public relations firms, and just a highly competitive process.

So every page of this report showcases the work and commitment and accomplishments from all of our Board members and staff. And so, hopefully you all received your copy of this now award-winning report and what an exciting accomplishment in this
Let's go to the next slide.

I wanted to spend a moment, too, just acknowledging that we marked the year with PCORI’s second Virtual Annual Meeting and wanted to congratulate all of you on an excellent 2021 Virtual Annual Meeting and what an impressive event. We had contributions from Board members in many different ways from the Steering Committee work to plan, to participation of facilitation in some of the plenaries and other sessions.

We had over 3,700 registrants and over 2,100 attendees for our Annual Meeting. And the average attendee lingered. They didn't just come and leave. Attending about 16 sessions and almost six hours of content.

So all of the content from the Annual Meeting can now be accessed online through the meeting platform and the links on our website.

We can go to the next slide.

So over the past year, we focused our efforts on both on what we do at PCORI and how we
work, and what we do really relates to the fulfillment of our mission. And we focused attention, as well, on the collaboration and teamwork and diversity equity and inclusion principles has critical pillars of how we work to accelerate fulfillment of our mission.

So I'm going to use this framing in order to walk you through some other achievements over the past year. Let's go to the next slide.

So what we do in fulfillment of PCORI's mission that we engage in and align with strategic priority setting and nimbly, efficiently, and effectively support funding activities in alignment with the Board approved Commitment Plan. So our strategic planning activities have really been central. As you can see here, we outlined some goals over the course of the year to develop the plan and respond to changes in the external landscape, and outreach, and listen, and engage and think about the implementation of our cost data provision in our legislation.

Our funding approaches included building
and implementing our COVID-19 response and executing our PFA programming and alignment with our Commitment Plan and implementing some rapid funding approaches. Let's go to the next slide.

So we'll take these little sections in turn and you can see here, our strategic planning activities have been broad and began with engagement of PCORI advisory panels back in 2020. And today we're at the point of talking with the Board of Governors about considering our proposed research agenda for posting for public comment. So this is a key milestone in progress over the year.

The Board has also worked with PCORI staff and identifying those principals for the next phase of PCORnet. And we talked about those earlier in the year and it guided the solicitation of the Phase 3 PCORnet Clinical Research Networks and Coordinating Center awards.

And last December, we also focused on our Commitment Plan and had the first 3-year Commitment Plan approved by the PCORI Board of Governors.

Really taking into account different scenarios and
then landing in a place that would move us forward. And I'll be talking more about that and a little bit later today.

So we'll also give you a brief update in a few minutes about our progress on implementation of priorities from our reauthorizing legislation. And we've begun with the Board and with Methodology Committee members to turn our attention to the focus of the Methodology Committee for PCORI’s next phase as well. Let's go to the next slide.

So a major milestone for the Board and for PCORI this year was the adoption of our five national priorities for health. And these priorities emphasize health, you know, placing a focus on outcomes more than the process for achieving them. And while establishing the national priorities was a first and major step in the larger strategic planning process. We now turn our attention to another major milestone this year that we've had in the development of our proposed research agenda, which we'll discuss shortly.

Let's go to the next slide.
So this year we also marked progress on our priority research areas in our reauthorizing legislation. We began with engagement of stakeholders, new and existing and diverse groups, as well as those with lived experience in interviews, webinars, workshops, and the like on priorities of maternal morbidity and mortality, as well as intellectual and developmental disabilities.

And in fact, we even had a convening this year hosted by the Methodology Committee on the methodological issues for research related to intellectual and developmental disabilities.

And all of this engagement drove over the course of the year of the development of a multi-year strategy and approach that will entail a combination of short-term and long-term efforts from funding opportunity announcements, to other evidence, products and plans for collecting data that's going to be important to all of these analyses.

So our first efforts are listed here on the right side of this slide, and they related to
expediting a few funding announcements based on our early stakeholder input. Our first effort was the embedding of special areas of emphasis in our broad announcements, but set aside funding. We had a focus on patient-centered maternal care and improved care for individuals with intellectual and developmental disabilities growing into adults.

And then we also had the Board approve the development of two targeted funding announcements. One on postpartum maternal outcomes and another on mental health conditions in individuals with intellectual and developmental disabilities.

We're learning from these announcements and from the community, and we know that more will be forthcoming as we continue to refine and develop forthcoming announcements to really meet these priorities. Next slide.

We also focused and made significant progress this year on the provision in our reauthorizing legislation to consider the full range of outcomes data and PCORI-funded research. And in a deliberate and stakeholder engaged approach for
PCORI, developed four key principles to guide our approach and responded to public comment. And they were approved by the Board in March of this year.

And we're now moving toward the development of further guidance for applicants and work with the Methodology Committee on the development of relevant standards.

And we recently convened a work group of the Board and PCORI senior staff to help define PCORI's position and strategy and integrate it into our Strategic Plan, and identify opportunities for PCORI to contribute to solutions that address rising healthcare costs and serve as a resource on patient-centered value.

And lastly, we've made a concerted effort to communicate about PCORI and our approach and focus on patient-centered evidence as highly relevant to the important national conversation on health care affordability. And if you haven't seen them, please visit these pieces in the Morning Consult or in the Health Affairs blog page that speak to these approaches that PCORI.
Let's go to the next slide.

So we talked about the PCORI's ongoing COVID-19 work and areas of focus back at our September Board meeting. And this has been a heavy area of focus over the past year with many achievements. And in summary, our efforts have focused on award funding with over 150 new awards at about $80 million of investment. Information sharing through things like horizon scanning and collaborating with PCORnet playing a major role in activities in partnership with other federal agencies.

And now as we chart our way forward, embedding topics of relevance to COVID-19 in our ongoing work. Next slide.

A substantial component to fulfilling our mission is in our 3-year Commitment Plan and the Board discussed several different scenarios back in December of last year and approved a 3-year Commitment Plan moving forward. And that's the scenario that's presented here, but the major accomplishment over fiscal year 2021 was meeting the
target for the fiscal year 2021 of $482 million in commitments.

Let's go to our next slide.

And I won't spend too much time here on this summary of our progress on Board approved candidate topics, except to mention that this was another outstanding achievement in working with the Board and the Science Oversight Committee. We piloted this expedited and enhanced process for the approval of candidate topics for several cycles with the Board. And in April, the Board approved the set of potential topics for development in several future cycles. And subsequently the Board approved and we launched six targeted PFAs in Cycle 2 and Cycle 3 of 2021. And we're on track for the others. And this was a huge effort across the PCORI and a true achievement over the course of the year.

Next slide.

So I'm going to just spend a moment here to mention that this year we've also taken attention to the language in our reauthorizing legislation that emphasizes a focus on both short- and long-term
activities, producing an array of evidence products that are on the side of shorter term, as well as longer term results.

So what you see here as a spectrum that actually shows a little bit of that tradeoff between speed and rigor. And on the left, you see summary level products that can be completed in about a year or so, but perhaps may represent less rigorous evidence, but nevertheless, they're highly valued by members of our stakeholder community when decisions need to be made, even when we don't have the benefit of the time factor for the rigorous evidence for some of the longer studies.

And as we move to the right, you'll see that we move toward these large multi-phase research trials and the rigor increases, but so does the time required to complete these projects. And so, our funding really has been supporting the full continuum and we spent time to make sure we're focused on that full range.

And our newest effort, which represented a significant achievement for PCORI is the Phased
trial or PLACER initiative, which funds that new form of large pragmatic clinical trials. And the PLACER announcement just yielded amazing results this year or in fiscal year 2021.

We had six awards for a total of $168 million. And this was a significant driver in us being able to meet the Commitment Plan target.

Let's go to the next slide.

I do want to give you some examples though, of some of those shorter-term evidence products, because they have also been important to that full continuum that we're supporting. And some of those include things like evidence maps and rapid reviews. And on the left here, you can see that this year PCORI completed a social needs evidence map, which charts social needs interventions that measure health outcomes.

And this map was recently published on our website. It's an interactive map and it captures study results and it's regularly updated with new data, allowing a user on the site to find the studies where an intervention has shown some
benefit, as well as to see where there could be evidence gaps, which also could actually help us generate new research topics.

And on the right side of the slide, you'll also see that they will be launching a new evidence report series called the Rapid Review Series. And this uses this expedited approach to synthesize existing studies and suggest research roadmaps for high priority topics in less time than it takes for traditional systematic review. And you can see some of those timely topics on the right, including video teleconferencing visits which have been so important during the COVID-19 pandemic.

Let's go the next slide.

Another major accomplishment this year related to resources for effective engagement in research, and our engagement team worked really hard in developing and launching a number of research resources. And most recently launched both Research Fundamentals, as well as a resource called Building Effective Multi-Stakeholder Research Teams.

And these resources provide training in
ways that allow individuals to learn about the
health research process and how to be involved in
patient-centered outcomes research, as well as the
importance of research team members working together
and understanding how to bring stakeholders into the
active members of the team and establish clear roles
and responsibilities that are needed to help
successfully complete a stakeholder-engaged research
project. Next slide.

So you're also soon going to be hearing
about some other work this year that is culminating
into an initiative called the Health Systems
Implementation Initiative. It's an exciting new
development. And I won't steal the thunder of the
team other than just to say, this represents another
major highlight of developments of innovative
approaches to expand PCORI's work in promoting the
implementation of evidence from PCORI-funded
research studies in real-world settings.

Let's go to the next slide.

So how we work is just as critical as
fulfilling our mission because it enables us to
fulfill the mission. And teamwork and collaboration is one component of how we work and this relates to setting our PCORI culture and thinking about our workforce and our workplace, as well as the organization transformation work that we're undergoing related to developing PCORI Next, our structure for the future.

Let's go to the next slide.

So the significant effort this year has been related to the PCORI Next. Our organization transformation that's really investing in our operational, cultural, and professional excellence, and we really have advanced those goals tremendously. And subsequently, you're starting to see some of the implementation and the recruitment of some of the leaders that will facilitate for PCORI's next phase.

Let's go the next slide.

And a key support to PCORI Next is a corollary effort to consolidate our space and support a collaboration and teamwork in a more integrated approach and pursuit of our mission. And
we are pleased to say publicly that PCORI's new offices will be at 1333 New Hampshire Avenue, and we anticipate being able to move there in the summer of 2022. This has been a remarkable effort over the past year and will be continued to be an important focus for us in fiscal year 2022.

Let's go to the next slide.

And how we work also includes our focus on diversity, equity, and inclusion. And we've developed a PCORI-wide diversity equity and inclusion initiative this year with both internal and external components. We have articulated our commitments both internally and externally, and PCORI's commitment to diversity, equity, and inclusion, we recognize is just critical to achieving our mission. And you can see those commitments here. Next slide.

And related to this, another major accomplishment was the bringing together of the PCORI and thinking about the main goals of a diversity, equity, and inclusion strategy around the three areas: learn, expand, and engage. And they
correspond to for PCORI's roles as an organization, a funder, and a partner.

And there's been progress in these realms as we think about learning to correspond to PCORI as an organization, we've been focused on things that enhance our data collection, strategic framework, to align with our DEI principles. And it's reflected in the addition of race and ethnicity filters on our portfolio, on our website and refinements of our procurement processes and procedures to include diversity, equity, and inclusion principles.

When we think about PCORI as a funder and talk about expanding, we have really been focused on research done differently and how we support it, the national priority emphasis related to equity as both PCORI and Board alike. And we recognize that our new national priority for health is one way to focus in this space, but that really equity is embedded across all of our national priorities for health moving forward.

We also have a focus on a health equity portfolio that will be stemming from that national
priority and a planned initiative that will come before the Board in a future cycle.

When we think about a PCORI as a partner and our strategy to engage, we are building efforts to capacity build and enhance and deepen our strategic partnerships. And our actions have been focused on opportunities to engage communities in our work and focus on diversity in our workforce development efforts, as well as increase our participation and opportunities to provide and collect relevant insight via things like thought leadership forums and expansion of dialogues about synergistic collaboration with other organizations and funders and agencies. And next slide.

So if we look forward into 2022, it's going to continue to build on all these substantial achievements in 2021. And as we look to fulfill our mission, we are anticipating that together with the Board will be able to adopt a Strategic Plan in the summer of 2022. And that we will start to embark on a new year in our Commitment Plan. And that year will be the beginning of the peak of that plan with
that front load of commitments that the Board was really interested in seeing at PCORI.

We’ll also continue our work on our perspective planning for topic development and continue the path on COVID-19 and reauthorizing priorities that are necessary to fulfill those priorities in our legislation.

As it relates to collaboration and teamwork in diversity, equity, and inclusion, the implementation of PCORI Next, and our office relocation will be large goals for 2022 and we'll continue our ongoing assessments and implementation of the strategies that we've begun for diversity, equity, and inclusion, and are really looking forward to moving some initiatives to the Board around health equity funding.

So with that, I'll turn it back to Christine to see if there's time for just a couple of questions. And I apologize for going quickly, but I know we're tight on time.

CHAIRPERSON GOERTZ: Thank you so much, Nakela. I just want to congratulate you and your
entire team for the tremendous effort that this presentation represents. I wish we had time to spend the entire day just going into much of this work in more detail, but thank you and please convey that our gratitude to your entire team for the incredible amount of work that this represents.

DR. COOK: Certainly. Will do. Thank you.

CHAIRPERSON GOERTZ: Are there any comments or questions for Nakela before we move to the next agenda item?

[No response.]

CHAIRPERSON GOERTZ: All right. In that case, I will ask you to continue on with our Commitment Planning.

DR. COOK: Fantastic. Well, today we're also going to revisit our Commitment Planning for the future. And as I mentioned last December, the Board approved our 3-year Commitment Plan, aligned to some really ambitious goals. And we've also began to track progress toward our commitment targets on a regular basis with the Board and place our commitments in context with each cycle, when we
review our slates for awards. So hopefully that's kept you up to speed on where we are with our Commitment Plans, but I'll do a little refresher and then talk about the proposed Commitment Plan for the next three years.

Let’s go to the next slide.

So this slide just basically details that model that the Board approved last year. And you may recall that represented on this slide are our yearly commitments from the past, and then the projections for the future. And in the past, our yearly commitments averaged maybe about $388 million per year.

And the projections with this model show this kind of front-loaded approach that peaks at about $600 million overall in commitments. And that translates to about $450 million in research commitments.

The steady state period that you see off to the right has this range of approximately $340 to $440 million per year, which accounts for basically a high and a low assumption about the PCOR fee,
1 which could have some fluctuation over the years.  
2 Let's go ahead to the next slide.  
3 So this is a snapshot of the 3-year  
4 Commitment Plan that supported that model that you  
5 saw on the prior slide for fiscal year 2021 through  
6 fiscal year 2023. And we have on the slide as well,  
7 fiscal year 2020, just include it as a reference.  
8 So the plan has four major funding lines or  
9 categories, and you can see the research category  
10 here, the dissemination and implementation category,  
11 infrastructure, and new initiatives. And the table  
12 really represents the roll-up of commitments into  
13 those four categories with $482 million in the  
14 Commitment Plan for fiscal year 2021. And the peak  
15 commitments of $600 million that began in fiscal  
16 year 2022.  
17 So meeting this plan in 2021 really  
18 required us to produce a full complement of the PFAs  
19 in most cycles, resulting in a substantial increase  
20 in research commitments. And we also discussed when  
21 we reviewed this Commitment Plan back in December of  
22 last year, the anticipation of a need of about a 15
percent increase in staffing to support this Committee Plan. And this is still in process, we're still recruiting. And as many of you know, it's quite a competitive marketplace. And so, we anticipate still needing that level of recruitment to fulfill even next year's commitments.

Let's go to the next slide.

So the big update is that in fiscal year 2021, as I've said before, we met the ambitious target, right? Of $482 million. And here you can see that the plan target in the column that's is labeled fiscal year 2021 Target was 482. And then the second column, you see the cumulative fiscal year 2021 commitment across the different funding categories with all the approved slates. And that was about $495 million or the actual commitments. So we were about $13 million above the target and exceeding the target in this scenario really did represent a strong suite of PCORI funding announcements and applications and awards in fiscal year 2021. And as I mentioned, our PLACER solicitation really was a strong driver of some of
those awards.

And the Commitment Plan really was intended to be an ambitious target rather than really a limit. And so, we wanted to push those awards early in this next phase of PCORI, kind of symbolized by that front-loading approach that the Board approved back in December.

I thought, just to give you a quick snapshot of some things that look different from our target to our actual could be helpful. And if you look down the two columns there, you do see that our dissemination and implementation line was a bit under target due to some of the COVID-19 delays related to the launch of the health systems implementation initiative that you'll hear about. That was originally included in our roll-up in our fiscal year 2021 plan. But now we'll be in our 2022 plan.

Infrastructure as well was largely under, due to a shift in timing of the PCORnet Coordinating Center awards. There was about $18 million that was programmed for fiscal year 2021 that has shifted to
fiscal year 2022 to accommodate solicitation timelines. And under commitments and new initiative funds, were really used to try to pick up or fund those larger than anticipated first slate of PLACER awards that we talked about and other robust research award slates. So that's how we were still able to make the target for fiscal year 2021 and anticipate as we move into 2022, that we'll have those commitments that I talked about that shifted into 2022 coming into fruition.

Let's go to the next slide.

So today the Board is actually considering the proposed 3-year Commitment Plan for fiscal year 2022 to 2024. And really the upcoming fiscal year 2021 cycles of awards are going to be represented in that Commitment Plan in 2022. And this is our first year of that peak funding in the model of trying to get to that $600 million in commitments.

I'll just take you through each of these categories briefly and talk about what's under them.

So the research category here represents half-investigator initiated and half-PCORI priority
topics, via special areas of emphasis or targeted
ingunding announcements. It also includes the full
range of the research spectrum, including
dissemination research, as well as methods research
and some of those short- and long-term priorities
products that we talked about.

In order to fulfill what's outlined here in
the research category, we'll need to offer the full
complement of PFAs in all three cycles, including
our broad PFA, our pragmatic clinical studies,
several targeted PFAs per cycle, and our PLACER PFA.
Under dissemination and implementation this plan
includes more than a doubling of our D&I commitments
for activities over our past average and includes
activities related to the dissemination and
implementation of results from PCORI-funded studies,
such as our Limited Competition PFA.

We do anticipate that as we're seeing these
results coming to fruition, that we're going to have
about twice as many results that are worthy of
implementation awards in the next few years from
larger investments that we've seen in the past and
things like our PCS PFA and our targeted topics.

I did want to note though, that this line
of dissemination and implementation in the
Commitment Plan, doesn't represent the full extent
of our investments in D&I, because we do have
components of the D&I activities in other lines.
For example, the communications and dissemination
research awards, or the engagement awards that are
focused on dissemination.

So the last category here around, or the
second to last, around infrastructure also focuses
on the acceleration of patient-centered outcomes
research funding and includes engagement awards, our
workforce related activities, as well as PCORnet.
Our engagement funding announcements around capacity
building, dissemination, as well as stakeholder
convening support are represented in this line.

And this line does represent an increase in
engagement funding for more awards to support that
higher level of research and D&I commitments. And
as it relates to the commitments for PCORnet
infrastructure, they're limited here. The funding
that's placeholdered is for the Coordinating Center, which was shifted from fiscal year 2021, as well as funds to fill emerging gaps or issues related to the current awards.

Originally, as I mentioned, there was about $16 million in 2022 for a PCORnet expansion or gap filling. But when you add in the $18 million, that shifted for the Coordinating Center, it's part of what you see here in this Commitment Plan.

We have similar levels of workforce funding in the infrastructure line here.

And then there's an average of about $50 million per year that's included in this new initiatives line for flexibility, for new initiatives, unanticipated opportunities, or new needs across research, dissemination and implementation or infrastructure.

And last year you may remember for fiscal year 2021, this is where that new initiative for PLACER was -- the $50 million was utilized for that.

So there are going to be several principles that will guide our efforts to align with
the Commitment Plan targets and goals that you see here. We'll continue with that accountability and visibility and our progress toward our Commitment Plan and goals at each cycle. We will have to make sure that we're thinking about the prospective planning of our PCORI funding announcements for our full fiscal year or even multi-year in a way that will help us to make sure we're planning to meet the targets. And this was a very successful effort last year. And we'd like to set that up again for the coming year.

We're also going to need to continue to ramp up, to maintain the level of solicitations and awards to meet the front-loaded approach. And there are components that are going to be critical to a successfully achieving the plan. I mentioned this longer-range topic planning that really utilizes the full spectrum of PCORI activities from special areas of emphasis, targeted PFAs or different types, even, as well as other evidentiary products. We also estimate that we're going to need to really fill the ongoing recruitments to reach our 15 percent
staffing increase for these key award activities.

So the item for approval today is this slide, the 3-year Commitment Plan for fiscal year 2022 to 2024 subject to an annual review and update by the Board similar to the way we're doing today.

And I think we can go to the next slide and we'd be ready for questions.

CHAIRPERSON GOERTZ: Thank you so much, Nakela. Danny.

MR. VAN LEEUWEN: Nakela, so I'm thinking about the national priorities and thinking about like what will be the impact on our Commitment Plan. And what's the timing that you see that adjustments might be made in our commitment allocations as you know, not the total amounts, but the allocations because of the priorities?

So if one of the priorities is, you know, my soap box, which is, you know, dissemination, implementation, and health communications. And to me seeing that, you know, cumulatively, there's been a four percent allocation for engagement, a three percent for D&I, which we are ramping up, but it's
becoming a priority, you know, it's gotten to the
level of a priority.

So what do you think -- what do you see the
impact and where?

DR. COOK: So maybe one thing I'll mention
is that a lot of what you see in the Commitment Plan
is the product of work that has to happen almost a
year prior in order to have the commitments really
show up in that year. And one of the things that we
wanted to do on a regular basis was this annual
review of the Commitment Plan with the Board in
order to make sure that we are planning for what we
would think would be changes or -- and the
distribution of commitments over the next year.

So if that helps a little bit with
timeframes, you know, the things that we're thinking
about now with our strategic priorities may shift
some things down the line. And so, we'd want to
start to build that into the annual review, but what
you're seeing for fiscal year 2022, now, really
reflects a lot of the things that are happening in
2021.
MR. VAN LEEUWEN: Thank you. That’s been helpful.

DR. COOK: Sure.

CHAIRPERSON GOERTZ: All right. Connie, then Mike.

DR. HWANG: Great. Thank you. And Nakela, thanks for that overview and obviously great progress in hitting a lot of these spending targets.

So when I look at the four major funding lines and the categories, particularly around dissemination and implementation, that one seemed for the reasons that you described, you know, some good examples of as to why some of the traction there was a little bit more limited. If I'm reading the materials correctly, it looks like, you know, we probably had only about 40 percent of the targeted funds that were sort of dedicated for spending there.

So you know, I'd love to hear from you in terms of where can we as the Board be very helpful in the years ahead to really help ramp that up. I know, I think we'll be hearing a little bit more
about the health systems implementation initiative,
but more broadly, like for that particular category,
I’d just love to get a sense of, you know, where you
think the greatest challenges and opportunities
might be. Since it seems to be the one that's a
little bit sort of lagging a little bit in terms of
the funds spent.

DR. COOK: Yeah, so a great question. It's
something that's come up at past Board meetings.

And one of the things that we've talked
about in the past is this -- the flow of investments
early on also dictate a bit in terms of what may be
ready for dissemination and implementation. And so,
we are at the point now that we're starting to see
those results kind of starting to rise. And so,
that's what's then built into the Commitment Plan
now in terms of an anticipation of having the
ability, I think, it's even another doubling that
happens around 2024, kind of trying to map through
what we've had in our investments to-date that when
they may be coming to fruition and predicting, when
those studies from PCORI funding could be ripe for

B&B REPORTERS
29999 W. Barrier Reef Boulevard
Lewes, DE 19958
[302] 947-9541
dissemination and implementation.

So that's part of the thread of seeing a ramp up that's happening, but it's a slower ramp up.

The other component that maybe I'll mention is that I did say this briefly, but that line can be a little deceptive because it does represent that piece that I just described. Things like moving certain types of research results into specific dissemination and implementation awards, but there are other components of what we've been talking about, both in our Strategic Plan and in other discussions with the Board that really do relate to dissemination and implementation that are represented in other lines on that budget.

So we have engagement awards that focus on dissemination that are represented in the infrastructure line. And we have our communications and dissemination research portfolio, the implementation science portfolio that we've been talking about, the national priorities will be represented in the research line.

So perhaps one of the things that could be
helpful for the Board to see is how across those 
lines, the commitments are lining up. And we may be 
able to do that for you in the future.

DR. HWANG: Yeah, Nakela. I think that 
would be helpful because if we're going to use that 
a little bit as sort of Dashboard metrics, yes. 
It would be great to be able to have a little bit 
more of a fuller accounting of those related 
activities.

DR. COOK: Yeah, that's great. Thanks, 
Connie.

CHAIRPERSON GOERTZ: Thank you. Great. 
Mike, and then Sharon.

DR. HERNDON: Yeah, I'll just be real 
brief. Nakela, thank you again very much. Great 
job presenting today. It's been really easy to 
follow and well done.

A couple of the things I want to comment. 
It is so nice to see that we're meeting our 
commitments. I mean, you know, for the last several 
years we've been falling short of that and I'm 
really delighted to see that we're actually above
some of the commitment, you know, over the last year or two. So that's awesome and great to see.

And, I've just wanted to -- from the Board perspective, at least this Board member's perspective, I really do appreciate the need for the increased staffing. You know, I think part of our struggles in the past, you know, to meet some of these metrics that we hold, you know, you and the staff accountable to, you know, has potentially put undue stress on the, you know, staff.

And so, I think it is imperative that you build your staff so that we can have the rapid turnaround. You know, the peer review and the, you know, all of the coordination that has to happen, you know, with these projects and with this aggressive agenda.

So thank you for thinking of that. And you know, I think it fits in beautifully with, you know, the staff work -- the staff working and the org chart design and all you've done.

And I just wanted to say that you have at least my full commitment to get the right people in
the right seats and enough of them to do the job, because this is important work. Thanks.

DR. COOK: Thanks for that comment Mike.

And I did want to make sure to mention that that's still something we think we're going to have to fulfill, and it's a work in progress, just given the timelines it takes to recruit, and you know, in some ways to recognizing that that can be a risk of achieving the targets. And so, we wanted to make sure we continue down that path of trying to get the right people and the right numbers at PCORI.

CHAIRPERSON GOERTZ: Thank you, Sharon.

DR. LEVINE: So just a quick question/comment, and I've been wondering -- and this follows on Connie's question, whether there is a way to highlight in the funding announcements if PCORI is particularly interested in research proposals that will lend themselves -- whose results will lend themselves to uptake, to dissemination and uptake by patients and health systems.

And I know that that's been part of the part of the language, but I just wonder if in our
effort to ramp up the implementable results, if you will, if we couldn't look at the language of the funding announcements and see if there isn't a way to emphasize that, you know, we're looking for impact and we're looking for results that have the potential to have an impact through uptake and implementation.

DR. COOK: Well, Sharon, we certainly can take a look at the language. We have it embedded in the PFA, as well as the review criteria, that applications are scored against. And so, what we may want to do is go back and make sure it has a level of emphasis that we really want it to have.

CHAIRPERSON GOERTZ: Great. Thank you. Any other comments or questions for Nakela on this particular agenda item before we vote?

[No response.]

CHAIRPERSON GOERTZ: All right. Before asking for a motion then, I'm going to ask Rachel, are there any updates to the attendance?

MS. BARNES: Yes, Robert Zwolak has since joined the call and we still have a quorum.
CHAIRPERSON GOERTZ: Great. Thank you so much. And in that case, I'm going to ask for a motion to approve the proposed 3-year Commitment Plan for FY 2022 through 2024 subject to annual review and update by the Board.

DR. HERNDON: Mike, so moved.

CHAIRPERSON GOERTZ: Thank you, Mike. Can I get a second?

DR. RHODES: Second, Karin Rhodes.

CHAIRPERSON GOERTZ: Thank you, Karin. Is there any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All right. I'm going to ask for a voice vote then to approve this final motion.

So all those in favor, please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[No response.]

CHAIRPERSON GOERTZ: Abstentions?

[No response.]

CHAIRPERSON GOERTZ: All right. Thank you.
We have, we have a Commitment Plan for the next three years. Thanks everyone.

I’m going to turn now to ask Sharon to lead our -- to kick off our discussion on the proposed research agenda that we hope that we're able to present for public comment. Hi Sharon.

DR. LEVINE: Great. Thanks so much, Christine.

And on behalf of the Strategic Planning Committee, I'm delighted that we've reached the point where we now have through an iterative process a proposed research agenda ready for posting for public comment.

I really want to thank the Strategic Planning Committee members who've spent a tremendous amount of time and effort thinking about it and contributing to this work, and the Board of governors for their thoughtful input and discussions, which led in October -- which led to substantial revisions and real focus on ensuring that the language of the agenda reflected the Board's intent in terms of the articulation of the
research agenda.

The research agenda is a framework for achieving progress on our national priorities for health, specifically through the strategy of funding comparative clinical effectiveness research, and will support PCORI fulfilling its mission in the unique space PCORI holds in the health research enterprise landscape.

And I'm going to turn it over to Nakela now to review the proposed research agenda that's been the result of this work.

DR. COOK: Thanks Sharon. So why don't we go ahead to the next slide. Thank you.

So you may recall that we discussed, I'm sorry. I'm just, I'm trying to pull up the right thing here. Okay.

You may recall that we discussed in our prior meeting on the research agenda essentially the development process and the timeline and what we'd hoped to accomplish when we made it to our December Board meeting. So today what we're going to do is review the proposed research agenda that's been
revised as Sharon mentioned, and ask that you consider for approval the proposed research agenda for posting for public comment and to support this, I'm going to go over a review of the revisions to the research agenda that were made based off of the Board's discussion during the October meeting a couple of months ago. And I'll also share with you a quick overview of some of the anticipated next steps for the research agenda following today's meeting.

And the Board vote is really focused on posting the research agenda for public comment. There will be an opportunity for the Board to hear what the public comments were and look at revisions to the research agenda before it's finalized. And that'll likely happen next year.

Let's go to the next slide.

So this should be a familiar slide to most of you. It shows the many activities that are encompassed by our Strategic Planning process. And we even recap some of those in the year review. And so, today we're really focused on the research
Let's go to the next slide.

So I wanted to come back to this diagram. It's one that you've seen before. It's the diagram of the components of our Strategic Plan. And it just helps, I think, in grounding some of the conversations for today.

So you can recall that the research agenda, as Sharon mentioned, provides the framework for achieving progress on the national priorities for health, specifically through the strategy of funding comparative clinical effectiveness research. And I bring that back to the floor because we heard in the October Board meeting the real importance of the emphasis of our strategy of funding comparative clinical effectiveness research.

And the other component here is that the research agenda help guides the development of a continuously relevant research project agenda, which is derived from an ongoing stakeholder engagement process. And the research project agenda is where the specific topics resides, such as intellectual
and developmental disabilities or maternal morbidity and mortality or topics that may be derived from stakeholder conversations.

The research agenda is the level where we'll be focusing our discussions today, which is that level up from the research project agenda. And we're focusing on the funding strategy for CER for now, which is reflected in the research agenda. And remember, that's just one of the several strategies though, to achieve progress on the national priorities. There are others that will be included in the Strategic Plan as well.

So let's go to the next slide.

So this slide just shares the background and the context for the development of the research agenda. And the agenda was developed from Board discussions that have taken place over the past year, which provided direction in terms of Strategic Planning inputs. And the directions also have helped inform various aspects of Strategic Planning, including the research agenda.

But we also had public input that informed
the agenda, including the public comment period from the national priorities for health, where some of the input on the thematic areas of importance for the agenda came up and the research agenda parameters that the Board helped develop also shapes the research agenda by outlining some of the key factors based on our authorizing law that we should take into consideration in creating a research agenda.

Let's go the next slide.

So these are those parameters, research agenda parameters that you've seen before, and I'm not going to go through them all. However, they're based on PCORI's authorizing law, preliminary stakeholder input, and the desire to allow for adaptability.

So the parameters that you see here helped shape the research agenda. There are things like accommodating a full range of outcomes important to patients and stakeholders and short- and long-term decision needs of stakeholders, and issues and topics across the lifespan or care continuum and a
full range of interventions.

The parameters also say that the research agenda should be in support of the national priorities for health and be responsive to emerging issues and new evidence, for example. And should take into account things like PCORI's unique role within the research ecosystem, even PCORnet as a unique resource and several other things that you see on this slide.

Let's go to the next slide.

So the Board and the Strategic Planning Committee's input really directed the work to develop the draft research agenda and the members of the Board and the Strategic Planning Committee all agreed that the research agenda should reflect the authorizing law, to support us being able to track and report our progress and impact the Congress. But it should also be clear and coherent and not to overly complicated. And also allow for flexibility and adaptability and updating over time and maintain a degree of broadness in the language to prevent restriction from emerging opportunities and even the
relevance to a number of important issues.

Also that it be based on discussions at the last Board of Governors meeting and that we heard the importance of clarity to the type of research that PCORI would fund.

Let's go to the next slide.

So as a reminder, these are the 10 draft statements for the research agenda that the Board discussed in October and provided feedback on at the October Board meeting. And I don't want to go through all of these. I just want to share them as a reminder of where we started. And subsequent to going through these in October and having the discussions with you, we heard a lot of input that's been helpful in thinking about the revision of the research agenda.

So let's go to the next slide.

So what we heard from you in October is that the language in the research agenda should continue to be action and solution oriented, and that terminology and word choice should be precise, consistent, and explicit rather than overly
conceptual to really make sure that everyone and our stakeholders understood what we were articulating.

We heard from you to be specific, to get the appropriate point across and minimize misinterpretation, but also not be overly prescriptive. We also heard the importance about the research agenda helping to shape the research project agenda. And there was broad support of the research agenda overall that we presented back in October, but some additional refinement was thought to be needed.

Some of that refinement included determining whether the research agenda consists of just statements and characteristics, or -- I'm sorry, just statements or the statements and characteristics together. And there was even discussion back in October about possibly including some of those characteristics more as illustrative examples, rather than characteristics under our research agenda statement.

We also talked about in October, possibly combining some complimentary statements such as the
elimination of health disparities and achieving of health equity and statements that were related to both of those. There was also a suggestion around perhaps thinking about combining things like the approaches for communicating evidence and implementation science.

We heard from you as well, to simplify the content on the research agenda while remaining very precise in our concepts and language.

So let's go to the next slide.

So the Strategic Planning Committee reflected on the Board's discussion and revised the research agenda and the restructured research agenda is refining the set of statements from 10 statements to six statements and included the characteristics as illustrative examples for additional descriptive information, rather than thinking about the research agenda having both a research agenda statement and characteristics.

We also, working with the Strategic Planning Committee, combined statements that have complimentary or related concepts. And that's one
of the reasons why we moved from 10 statements to six statements. And the committee also simplified the content by trying to focus on the statements and revising the language to be more explicit and consolidating some of the illustrative examples.

So I want to walk you through the proposed research agenda that we're presenting to the Board for consideration.

Let's go to the next slide.

So here it is, it's now comprised of six statements that all begin with "Fund research that," and this is to emphasize the connection to the funding of comparative clinical effectiveness research. And as we go through these, I'll also highlight feedback from the Board and how it was incorporated in the revisions.

So let's look at the first one, which is fund research that fills patients and stakeholder prioritized evidence gaps and is representative of diverse patient populations and settings.

And so, this statement combines the prior ones that were related to filling patient and

B&B REPORTERS
29999 W. Barrier Reef Boulevard
Lewes, DE 19958
[302] 947-9541
stakeholder prioritized evidence gaps and the use of
data representative of diverse patient populations
and settings. So it brings both of those statements
together into the one that you see on the slide
here.

The second statement, fund research that
aims to achieve health equity and eliminate health
and healthcare disparities reflects the merging of
statements that were related to achieving health
equity and elimination of health and healthcare
disparities. And this is what we heard from the
Board as our recommended combination. And so, we
tried to reflect it here.

The third one here is, fund research that
builds the evidence-base for emerging interventions
by leveraging the full range of data resources and
partnerships. And this is a statement that's also
the result of combining two prior statements. One
that was focused on building the evidence-base for
emerging interventions, which included reference to
the importance of partnerships. And it's combined
with a statement that was actually related to
optimizing the full range of data resources.

So the fourth statement here, fund research that examines the diverse burdens and clinical and economic impacts important to patients and other stakeholders. This one actually maintains a bit of a separation of this statement from some of the others because of the importance of this new work around economic impacts and its linkage of economic impacts to clinical outcomes. So we didn't combine this one with others. We just tried to make it clear.

The fifth statement around fund research that focuses on health promotion and illness. I'm sorry, health promotion and illness prevention by addressing health drivers that occur where people live, work, learn and play was one that had a lot of discussion with the Strategic Planning Committee. This was a simplified statement and focuses on the research on health promotion and illness prevention by addressing health drivers that occur where people live, work and play. And it connects addressing health drivers outside of the clinical setting as
being a key area for health promotion and illness prevention.

   And the last statement here, fund research that integrates implementation science and that advances approaches for communicating evidence so the public can access, understand, and act on research findings, takes this approach of combining the implementation science aspect and communicating evidence from our research findings and tries to do it in a way that still maintains the distinct concepts while also recognizing that there's a relatedness between.

   And this is something that we specifically heard at the Board meeting as two areas that maybe could be combined into a statement.

   Okay, let's go to the next slide.

   So, as I talked about before, some of the illustrative examples have also been updated as a result of the combination of statements. And what we're trying to do with these illustrative examples is give some explanatory context to each of the statements based on the feedback from the Board.
But also keep them separate from the official research agenda. And so, you'll even see we use some call-out boxes to try to really distinguish that these illustrative examples are just examples of how the research agenda statement may play out.

I want to take you through a few of these, just so that you get the feel of how we're thinking about these illustrative examples as well.

So for the first research agenda statement here around funding research that fills patient stakeholder prioritized evidence gaps and is representative of diverse patient populations and settings. You see three illustrative examples. One that focuses on research on topics and outcomes of relevance and value to patients and stakeholder communities. Another that focuses on research that recruit study participants that are representative of communities most affected by conditions. And the third one that's about research that involves investigators that reflect the population or community where the research is conducted and for whom the research is intended.
So those three examples are thought to provide some context into how that agenda statement may translate into research items for PCORI.

The second statement that you see here, fund research that aims to achieve health equity and eliminate healthcare disparities has three illustrative examples as well. And the first one talks about research across conditions, populations, and subpopulations on topics where disparities and health outcomes occur. The second one focuses on research on innovations for health systems that try to practice change to promote equitable care. And the third one focuses on research that supports and develops the talent of diverse early career investigators and the healthcare workforce.

We can go to the next slide.

So here you see our next two research agenda statements, fund research that builds the evidence base for emerging interventions by leveraging the full range of data resources and partnerships. And you see three illustrative examples here. One that talks about leveraging...
evidence synthesis and stakeholder engagement.
Another that focuses on innovations that are
identified through relationships with federal
partners. And a third that talks about using
optimized methods of data capture that are inclusive
of diverse sources of information.

The next statement around examining diverse
burdens and clinical and economic impacts relevant
to patients and other stakeholders has two
illustrative examples. Research that engages
patients, caregivers, and other stakeholders in
identifying important outcomes, unintended
consequences, burden, and economic impacts, as well
as research that assesses the full range of factors
that influence health outcomes.

And let's go to our last set, the next
slide.

So here you see our last two statements.
One on funding research that focuses on health
promotion and illness prevention. And the three
examples here, focus in on cross sector
collaboration with organizations that have expertise
in social determinants of health. The second
illustrative example focuses on research on upstream
topics, such as social determinants of health. And
the third one focuses on research that examines the
use of an investment in health promoting resources
in the community.

And then the last research agenda statement
around research that integrates implementation
science and advances approaches for communicating
evidence has four illustrative examples. And really
four examples are used here because of the
complexity of what's included in this research
agenda statement and wanting to give examples that
hit different parts of that complexity.

So the first illustrative example focuses
on research that studies the effectiveness of ways
to get information to the right people at the right
time, in the right way. The second example focuses
on approaches for rapid dissemination of evidence.
The third one is an example that focuses on research
on the effectiveness of implementation strategies.
And the fourth one is focused on research that
assesses methods for explaining things like uncertainty, applicability, communicating risk.

So this is kind of, in sum, what we've put together with the Strategic Planning Committee, for the research agenda statements and some illustrative examples that will provide context to our stakeholders when they're reviewing the research agenda.

Let's go to the next slide.

So I'm going to wrap it up by just noting the timeframe for adopting the research agenda, just so that you know what's coming next.

And so, today we'll have you consider what I've just presented on behalf of the Strategic Planning Committee for the research agenda for public comment. And if it's approved for public comment, we anticipate that we'll start shortly after this meeting.

Then the public comment period would likely go through late January and then following the public comment period, the research agenda would be revised accordingly.
And then the Board would be expected to review the revised research agenda and consider it for adoption at its March meeting.

So we can go to the next slide.

And with that, we welcome your comments and ask if there's concurrence on the revisions made by the Strategic Planning Committee to the proposed research agenda and following discussion, hopefully can move toward a vote.

CHAIRPERSON GOERTZ: Thank you, Nakela, Sharon and all the members of the Strategic Planning Committee. It's very exciting to be at this point to be able to send this agenda out for public comment.

Does anyone have any questions or comments or concerns about the about our revised proposed research agenda at this point?

[Inaudible responses.]

CHAIRPERSON GOERTZ: All good? Thumbs up. Thank you.

It's very hard not to see people's faces so -- okay. Thank you. Thank you.
All right. Well seeing some thumbs up there then I'm going ask Rachel, if there's an update to the attendance.

MS. BARNES: No updates and we still have a quorum.

CHAIRPERSON GOERTZ: Thank you so much.

In that case I would like to ask -- could we have the next slide? The motion slide? There you go. Thank you.

I'd like to ask for a motion to approve the proposed research agenda for posting for public comment.

MR. VAN LEEUWEN: So moved. This is Danny.

CHAIRPERSON GOERTZ: Thank you, Danny.

DR. LEVINE: This is Sharon, second.

CHAIRPERSON GOERTZ: Thank you very much, Sharon.

All right. Is there 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: All right, thank you.

The next item on the agenda is a break we will return at 2:00 p.m. Eastern time. We have a number of our slates that we will be approving as well as some very exciting PFAs. So we will see you again at two o'clock Eastern time.

[Recess.]

CHAIRPERSON GOERTZ: Welcome back everyone. Why don't we get started.

So where I'm going to ask Nakela to give us a broad overview of our award slates, and then she'll turn it over to Jen DeVoe, who will actually introduce the slates today.

DR. COOK: Excellent. And thank you. So I'll just begin with, as you may recall, we discussed approaches to monitoring our progress against what's laid out in the Commitment Plan every
time we look at slates of awards, so I want to give you this context for the slates under consideration for approval this cycle, as well as provide you with some context of how these slates compare to some of the historical approaches within our PFAs.

And just to make sure that all the Board members remember that as we begin this review of our slates, recall that all of the ones that are presented today have gone through that multi-step process of merit review, staff review, and relevant selection committee review.

Okay, let's go through the next slide.

So today the Board is going to consider the following three slates for approval. Two of them are research solicitations and one from an infrastructure solicitation, and they total together about $67.5 million. And overall we're within the Commitment Plan accounting for some of the shifts of funds that we talked about in our Commitment Plan discussion, where we had related to infrastructure, some funds that shifted from fiscal year 2021 to fiscal year 2022.
Our Cycle 1 overall had, I would say, more limited offerings. We had fewer PFAs in cycle, one of 2021. As you may recall, at that time, we were working through several expedited COVID-related funding announcements, and those hit the Commitment Plan and fiscal year 2021. So they won't really show up in our Commitment Plan for 2022 like the other slates that you're looking at today.

Cycle 2 did have a more Targeted PFAs. And so, as we look forward in terms of what we may see in our future Board meetings related to slates, you'll see that in our future cycles, you'll have more targeted PFAs to review. Let's go to the next slide.

So this slide just kind of demonstrates how the funding cycles for the pragmatic clinical studies or the PCS award slate fits into the larger context of data related to letters of intent, the applications and funding rates compared to our historical average. And what you can see here is that we had a pretty robust response to these announcements with 36 letters of intent submitted.
And while this is lower than our historical average this could relate to the fact that the timing of issuance was essentially when we began issuing PCS every cycle and are likely to see more of a distribution of letters of intent across multiple cycles. And that'll be different than our historical, where we tended to have only two offerings of pragmatic clinical studies each year.

In addition, we also issued the PLACER announcement in Cycle 3 of 2020, which likely captured a lot of our large pragmatic trial applications. And so, we may have seen a little bit of a drop-off with the PCS and the cycle following the PLACER announcement.

We did invite over half of those that submitted letters of intent to this solicitation to submit applications and received almost 85 percent of those that were invited. And we're proposing today three for funding, and we'll continue to watch these trends for Cycle 2 of 2021 as you see on the right side of this slide, as we ramp up offerings for different PCORI funding announcements, and we
may have to adjust as need be, given we are increasing the offerings in the future cycles.

Okay. Can we go to the next slide?

This slide demonstrates how the Cycle 1 2021 broad PCORI funding announcement slate fits into the larger context and how they compare to the previous cycle. And what you can see here is that this table is really intended to provide some insight into whether a given cycle is typical or a departure, and the slate is smaller than previous, and may have been a bit unusual because we didn't offer the broad PFA in Cycle 2 of 2020.

We accepted only applications that had differed from Cycle 1 because of the pandemic.

And you can see a few things with the slate, there were 146 letters of intent, 60 percent were invited to submit applications and 65 percent actually submitted. And we're proposing six here for funding.

Cycle 3 of 2020 was the first full cycle following the pandemic disruption and the higher numbers that are there are likely to be a result of
that. And so, as we continue to look forward, the next broad PFA slate that'll be considered will be our Cycle 2 of 2021 that you see on the right of the slide and then Cycle 3 of 2021. And thus far they're looking similar percentage-wise to what we've seen in the past. And historically, we have seen a dip in applications in Cycle 2, and we're trying to understand that trend as well.

And so, the fact that we've added the option to defer applications from invited letters of intents to later cycles may be complicating some of the interpretation of these numbers and trends. And after a few more cycles, we may be able to get a better understanding of this and speak to it a little bit more in future Board meetings.

But for now it's the first time that we're issuing the full complement of PFAs as we talked about in the Commitment Planning discussion and all of the cycles. And we may also be seeing some shifts related to that. And so, it's one of these things that we're monitoring over the next several cycles and hope to be able to tell you a little bit
more about what's happening there as we learn and do
some analysis of our aggregate numbers.

Let's go to the next slide.

So this slide demonstrates how the Phase 3
Coordinating Center for functions for PCORnet award
slate fit into the larger context and how it
compares to historicals. And what you can see here
is that Phase 1 was that design phase for the
network and was funded in 2014 at a level of about
$14 million.

And Phase 2, which began in 2016, focused
on capacity building and for this solicitation,
PCORI actually invited an application from the
organizations funded to participate in the
Coordinating Center for PCORnet. And one
application was funded then at a level of $39
million.

And then Phase 3, which is what we're
putting before you today is this period of
optimization. And the PFA here was a limited
competition PFA where PCORI solicited applications
from prime organizations that are currently funded
to participate in the Coordinating Center. And nine applications were submitted and five are being proposed here for funding for a total of $18 million.

And as you can recall, the Commitment Plan target had that total of $450 million for research PFAs and funding of these slates -- can we go forward to the next slide?

I think yes, as you can recall here, the Commitment Plan target has a total of about $450 million for research PFAs. And so, funding of these slates presented to the Board for consideration today would be about $49.5 million of the research commitments. And the Commitment Plan target for infrastructure had about $60 million, inclusive of engagement PCORnet, and the workforce awards and $18 million of that was intended for the PCORnet infrastructure and it's the amount that's being proposed in the slate before the Board today.

So there are sufficient funds remaining in our future cycles for research and infrastructure funding. And we're not proposing any modifications

B&B REPORTERS
29999 W. Barrier Reef Boulevard
Lewes, DE 19958
[302] 947-9541
to the Commitment Plan at this time, but we do anticipate that Cycle 2 and particularly Cycle 3, hopefully, will have larger slates for us given we have targeted PFAs that will appear in Cycle 2 and Cycle 3.

So with that, I'm going to pause and see if there are any questions and turn it back to you, Christine, before we go over the slates.

CHAIRPERSON GOERTZ: Thank you, Nakela. Are there any questions or comments from the Board regarding our proposed commitments for this particular slate?

[No response.]

CHAIRPERSON GOERTZ: All right. In that case, I'm going to ask Jen to introduce the award slates.

DR. DeVOE: Great. Thanks. I'm really honored to be here on behalf of the Selection Committee and our chair, Dr. Barbara McNeil and the rest of the committee. We are here to recommend the three award slates that Dr. Cook just highlighted and set into context for us. Thank you, Nakela.
So this is a long process, as you know, so in October and November, after many months of merit review and staff review, our Selection Committee met to consider these slates for the Cycle 1 2021 brought in pragmatic clinical study PFAs and the Coordinating Center functions to advance Phase 3 of PCORnet. And as usual, our committee engaged in many robust discussions, reviewing the merit scores, considering the program staff recommendations, working with program staff to resolve issues that were raised in review, assessing programmatic fit, portfolio balance, and consistency with funding announcements.

Following these deliberations, our Selection Committee recommends these three slates for the Board's approval for funding today, I will now turn it over to Carly Khan to present the first slate. Thanks Carly.

DR. KHAN: Great. Thanks so much, Jen. Hi everyone. My name is Carly Khan. I'm an Associate Director with the Healthcare Delivery and Disparities Research Program, and I'm pleased to
present the Cycle 1 2021 pragmatic clinical studies overview and slate recommendations for your consideration today.

    Just briefly, the pragmatic clinical studies PFA has a direct cost cap per study of $10 million and seeks to fund clinical trials, large simple trials, or large-scale observational studies addressing one of the PCORI's five current priority areas.

    And if I could just have the next slide, please.

    And so, as you can see here, these Cycle 3 studies are being recommended for funding by the Selection Committee. And each study proposed is a randomized multi-site controlled trial. And very broadly, these studies will examine the comparative effectiveness of interventions to improve clinically significant depression, address chronic pain, and support smoking cessation in underserved patients. And the total funds requested for the PCS slate this cycle is $23.5 million.

    Next slide, please. I'll turn it back over.
for discussion and vote.

CHAIRPERSON GOERTZ: Thank you so much Carly.

Just a note before we begin any discussion on this particular slate, Barbara McNeil let us know that she intended to recuse herself. She’s actually not present, but I wanted to make that announcement. If any other Board member believes they should recuse themselves. Please do so.

All right. Are there any comments or questions for either Jen or Carly?

[No response.]

CHAIRPERSON GOERTZ: Okay. Rachel, are there any updates in attendance? Do we still have a quorum?

MS. BARNES: Yes. Kate Barry, Connie Hwang, and Kathleen Troeger have left the call and we still have a quorum.

CHAIRPERSON GOERTZ: Thank you.

All right. I'd like to ask for a motion then to approve funding for the recommended slate of awards from the Cycle 1 2021 pragmatic clinical
trials PFA.

DR. FERNANDEZ: So moved.

CHAIRPERSON GOERTZ: Okay, Alicia. Thank you. Can I have a second?

DR. ZWOLAK: Second.

CHAIRPERSON GOERTZ: Thank you, Bob. Is there any further discussion?

[No response.]

CHAIRPERSON GOERTZ: I'm going to call for a voice vote then. All those in favor, please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[No response.]

CHAIRPERSON GOERTZ: Abstentions?

[No response.]

CHAIRPERSON GOERTZ: All right. Thank you. Now we're going to move on to our next slate. This discussion is going to be led by Steve Clauser and Holly Ramsawh.

Steve and Holly, are you ready to go?

DR. CLAUSER: Yes, we are.
CHAIRPERSON GOERTZ: All right.

DR. CLAUSER: Thank you. I'm going to be presenting the two proposed funding slates for the addressing disparities and improving health care systems priority areas. And then, Holly Ramsawh will be presenting the two funding slates proposed for the priority areas of assessment of prevention, diagnosis, and treatment options and methods. Next slide.

This is the consensus of slate projects for the Cycle 1 2021 addressing disparities and improving health care systems priority areas that the Selection Committee is recommending for funding.

The first study at the top of the slide is a clinical trial and examine strategies to improve access in care for children of color who have inadequate access to mental health services.

The second study just below that on the slate addresses our congressionally mandated special area of emphasis related to maternal mortality and morbidity and compare strategies to improve outcomes and reduce disparities in pregnant women with
general herpes simplex virus infection.

The third study addresses congressionally mandated areas of intellectual and developmental disabilities, and compare strategies to improve long-term care planning and support services for individuals with IDD and their caregivers during the critical transition from adolescence to adulthood.

And the fourth and final study on this slate is a clinical trial, which compares follow-up visit strategies for children hospitalized with acute illnesses.

Next slide. Now, I’ll turn it over to Holly Ramsawh.

DR. RAMSAWH: Okay, thanks.

Thank you. I'm happy to present the slates for both the assessment of prevention, diagnosis, and treatment options and improving methods for conducting PCOR. For the first slate, this is a pragmatic randomized controlled trial that seeks to compare the effectiveness of a non-steroidal anti-inflammatory drug versus a low dose opioid analgesic regimen on pain management.
And for the second slate, the overarching objective of the project is to develop new statistical methods for instrumental variable designs that incorporate modern machine learning approaches.

Next slide please.

And now I'll hand it back to Dr. Goertz for a vote.

CHAIRPERSON GOERTZ: Thank you, both, Steve and Holly.

Before we begin any discussion, I want to let you know that the following Board members have notified us of their intention to recuse themselves from the deliberative discussion and vote. Those members are Kara Ayers, Mike Lauer, Sharon Levine, James Schuster, and Christopher Friese.

If any other Board member feels that they should recuse themselves, please do so. I'd like to now open it up for discussion.

[No response.]

CHAIRPERSON GOERTZ: All right. Hearing no requests for discussion, then I'd like to ask for a
motion to approve funding for the recommended slates of awards from the Cycle 1 2021 Broad PFAs.

DR. HERNDON: Mike, so moved.

CHAIRPERSON GOERTZ: Thank you, Mike.

DR. LEVINE: Sharon, second.

CHAIRPERSON GOERTZ: Thank you, Sharon.

Actually, Sharon, I think you're recused.

DR. LEVINE: I take it back.

[Laughter.]

DR. ZWOLAK: It's Bob, second.

CHAIRPERSON GOERTZ: Okay. I heard Bob.

So let's go with Bob. Thank you.

All right. Is there any further discussion?

[No response.]

CHAIRPERSON GOERTZ: Once again, I'm going to call for a voice vote. All those in favor, please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[No response.]

CHAIRPERSON GOERTZ: Abstentions?
[No response.]

CHAIRPERSON GOERTZ: Okay, thank you.

I'm now going to ask -- I'm going to turn it over to Sharon Levine and ask her to chair the next item on our agenda. Sharon, are you there?

DR. LEVINE: [Presiding.] I am. Thanks so much, Christine. And Christine has asked -- has said that she needs to recuse herself from this discussion. So I'm going to introduce -- to present the Phase 3 of the PCORnet Coordinating Center functions. Dr. Laura Lyman Rodriguez, who will present the proposal to us.

DR. LYMAN RODRIGUEZ: Hi, thank you all very much. And I am excited to be here to talk about this recommended slate with you all for the Coordinating Center functions for Phase 3 of the PCORnet.

So if we could go to the next slide.

Before we talk about the specifics of the PFA, I just wanted to remind folks briefly about the work that the PCORnet Priorities Working Group of this Board did last winter to develop a set of
prioritizing principles for PCORnet and its future funded activities, to provide guidance to PCORI staff on the parameters for Phase 3 of PCORnet, as well as guidance that can inform our ongoing program oversight once the awards go into effect.

These principles fell into three broad categories around patient-centeredness. An emphasis on utilizing the network for studies with a national scope, as well as promoting collaboration, partnerships, and optimizing governance systems that occur across the network. These principles, as I mentioned, were discussed -- developed and discussed last winter and the Board approved them in January.

And at that same meeting, the Board approved the development of the funding opportunities to go forward with Phase 3. And you can see the breakout for the two components of this initiative in the table below.

And what we'll be talking about today is the $18 million that were approved for spending on the Coordinating Center function.

Just also a brief note before we move on to
the PFA that the working group will be continuing its work in coordination with the ongoing Strategic Planning process that PCORI is in the process of, and so, they will be working and you'll be hearing more from them in 2022.

Next slide please.

To provide an overview of the objectives within the Coordinating Center functions, I also want to begin by highlighting that in response to the prioritizing principles from the work group, this has been structured differently than these functions were provided in the past. And so, there are five functional scopes of work that are intended to work together rather than one awardee. And the way this was put into place, eligible applicants for the PFA were able to apply to one or more scopes within the PFA.

The specifics for the different functional scopes are of course, beginning with the Program Management Office to facilitate the logistics and coordination across all of the network activities. Also with a particular focus on ensuring that there
is coordination and integration of all of the Coordinating Center functions across any awardees. Second then, is the maintenance and development of the common data model. Moving then to scope three, where we will have the functions related to the query functions and analytic tool development to enable multi-site network research to be accomplished through the PCORnet.

Scope four is an explicit attention to communications and particularly external communications about PCORnet’s capacities, their assets, and collaborative opportunities to, again, speak back to the prioritizing principles in terms of promoting PCORnet as a platform for research studies that are national in scope.

And finally then, is the fifth functional element is a new function for the Coordinating Center. And that is one that is dedicated to engagement of all the PCORnet stakeholders. Really working to also capture the learnings and best practices from across the network sites and
promoting awareness of them, disseminating them to other networks, as well as to others to make sure that those best practices are learned and able to be capitalized upon across all of the network activities.

So with that, we can go to the next slide, which has the recommended slate with the projects recommended by the Selection Committee for each of the functional scopes of work. Because again, these were to be awarded individually. And you can see the titles here. And at this point I will turn it back to Dr. Levine for any discussion and the vote.

DR. LEVINE: Thanks so much, Laura.

And before we open this for discussion, the following Board members have notified us of their intention to recuse themselves from the discussion and from the vote on the infrastructure slate award slate. I've already mentioned Christine Goertz, Jennifer DeVoe, Mike Lauer, James Schuster, and both Michelle McMurry-Heath, and Barbara McNeil, who had previously indicated their intention to recuse themselves but are unable to attend a meeting.
So can I get a motion to approve funding for the recommended slate of awards from the Cycle 2 2021 Coordinating Center functions to advance Phase 3 of PCORnet. And then, with the motion and a second, we'll open it for discussion.

DR. HOWERTON: Russ Howerton, motion.

DR. ZWOLAK: Bob, second.

DR. LEVINE: Thanks. Okay. Can I ask for any discussion, questions?

[No response.]

DR. LEVINE: Okay. Then I will call for a voice vote to approve the Cycle 2, to approve the infrastructure awards slate all in favor.

[Ayes.]

DR. LEVINE: Opposed?

[No response.]

DR. LEVINE: Any abstentions?

[No response.]

DR. LEVINE: The motion passes. Great.

Okay. I will turn this back to Nakela to provide an overview of the targeted PFA development to be considered for approval today.
DR. COOK: Excellent. Well, thank you so much, Sharon. And I'm looking forward to talk to a little bit about the targeted PFAs that are being put before the Board for consideration in the context of that expedited and enhanced process we spoke about for the development of PFAs.

So let's go to next slide.

So under that process that we undertook with the Board for development of PFAs, while Strategic Planning is underway, we launched six targeted PFAs to date for a total of $260 million. And you can see them outlined here, covering maternal outcomes, as well as mental health conditions in individuals with intellectual developmental disabilities, urinary incontinence in women, as well as the treatments for migraine prevention, and healthy aging, and multimodal interventions to prevent osteoporotic fractures. And all of these different topics took different approaches to the PFAs.

And we're really excited to see how they pan out so that we can have some insights as we move
forward with this next approach for the following year.

But in addition to these targeted announcements, we also released what we were calling special areas of emphasis within our Cycle 3 broad PFA, and that included tele-health or chronic disease management amongst vulnerable populations with complex needs as well as a special area of emphasis on addressing systemic racism, discrimination, and bias. And the idea here is that these special areas of emphasis may actually help inform targeted PFAs and tailor them down the line.

So this approach that we took on where we were prospectively identifying topics really has been critical and allowing us to keep pace with two to three targeted PFAs per cycle to meet the Commitment Plan. And as I mentioned, when we were talking about the slates, these targeted PFAs that we'll see coming into fruition, even in Cycle 2 and Cycle 3 that are listed here on the slide are what's really going to help us to meet the Commitment Plan.

We also know that we're starting to see
some of the letters of intent and applications coming in, where we may have robust responses and where we may have to tweak or resubmit and -- I should say, tweak or allow for resubmissions in order to reach some of the goals of PFA.

So that's another component of this approach.

Let's go to the next slide.

So back in April, the Board approved that large set of candidate topics for targeted PFAs or special areas of emphasis development through the 2022 funding cycles. So you can see on the left, the topics that have moved forward as targeted PCORI funding announcements. And today we're going to discuss substance abuse in youth -- and substance abuse in youth, as well as delirium for release in Cycle 2 of 2022. And the remaining topics that you see on the right of the slide are still under development.

And remember, all of these are in addition to COVID-19 related topics, maternal morbidity and mortality, and intellectual and developmental
disabilities related topics.

And as we move through this, kind of thinking around approval of a set of candidate topics for TPFA development. But one of the things that we talked about, and we're starting to see this to be a helpful thing for PCORI, is that doing this allows for some longer-range planning, both for the community that applies to PCORI, as well as within PCORI itself. It helps to focus the staff resources in the target areas and provides a greater advanced notice for the researcher and stakeholder communities.

It also can increase the readiness of application submission and may result in a greater number of fully developed applications.

So you'll notice on this slide, that there are some of the topics that have an asterisk, and that indicates that they were intended as special areas of emphasis. And in the broad announcement, having that special area of emphasis could really serve as a signal to get attention to a topic early on. And as I mentioned, allow us to build on an
approach with a targeted solicitation that follows.

Let's go to the next slide.

So today the Board is going to consider the two targeted PCORI funding announcements that were recommended by the Science Oversight Committee for Cycle 1 of 2022. And the topics are considered important and feasible in the timeframe to maintain pace on meeting the Commitment Plan and include standard approaches, stakeholder outreach, literature review, and relevant portfolio review.

And the Board may also recall that we'll need about two to three targeted PFAs for the next several cycles to meet our Commitment Plans. And so, these are the two for the Cycle 1 2022. Brief interventions for adolescent alcohol use up to $30 million being targeted for funding. Prevention, early identification and treatment of delirium is the second for up to $30 million of targeted funding. And this totals up to $60 million.

So both of these are presented today as part of that set of the candidate topics for targeted PFA development. And they really do
represent a wider range of study duration and
funding level to allow for different study designs
and sizes. And we’re also offering more than one
cycle as warranted to allow for deferrals and
resubmission.

So with that, I will turn it to, it looks
like Alicia is ready to go.

DR. FERNANDEZ: Good. Oh, thank you
Nakela.

So on behalf of the Science Oversight
Committee, I am pleased to recommend to the Board
the development and funding of the two targeted PFAs
that Nakela just highlighted and set into context
for us. The SOC has discussed and approved these
topics for the Board's consideration and looks
forward to recommending additional topics to the
Board in the future.

But today's topics are brief intervention
for adolescent alcohol use. And that one will be
discussed by Els Houtsmuller. Please go ahead Els.

DR. HOUTSMULLER: Yes. Thank you, Alicia.

Next slide please.
So this -- the research question for this proposed targeted PFA focuses on the comparative effectiveness of brief behavioral interventions that are adapted for adolescents ages 12 to 17 to address alcohol use.

Next slide please.

The PICOTS for -- the proposed PICOTS for this PFA are shown on this slide. Brief intervention should be adapted for adolescents and delivered in primary care and/or school settings. Alcohol use would be a required primary outcome, and we would strongly encourage inclusion of other substance use.

And then there are several other outcomes of interest also listed on this slide. We would require a 12-month follow-up. And the total amount that we are requesting is $30 million. We're estimating that we would release this PFA up to three cycles, and we're expecting to fund three-to-five studies with a maximum project duration of up to five years.

Next slide please.
I will now hand it back to Alicia for all discussion and a okay.

DR. FERNANDEZ: [Presiding.] Okay, I will call for a motion to approve the development of this targeted PFA on brief interventions for adolescent alcohol use.

DR. AYERS: So moved, Kara.

DR. FERNANDEZ: Thank you, Kara. Do we have a second?

DR. HERDON: Mike, second.

DR. FERNANDEZ: Thank you, Mike. Is there discussion?

[No response.]

DR. FERNANDEZ: Hearing no discussion. We'll move to a voice vote to approve the final motion.

All in favor.

[Ayes.]

DR. FERNANDEZ: All opposed?

[No response.]

DR. FERNANDEZ: Any abstentions?

[No response.]
DR. FERNANDEZ: So I look forward and hope the research community reacts to this great TPFA. Thank you all.

I now -- we will know have a presentation from Yewande Akinbami on the second PFA on an important topic, the development prevention, early identification, and treatment of delirium.

Please go ahead, Dr. Akinbami.

DR. AKINBAMI: Thank you, Alicia.

Next slide please.

So our proposed research question is what is the comparative effectiveness of evidence-based single and/or multicomponent interventions to improve prevention, early identification, or treatment of delirium in older adults?

Next slide please.

The PICOTS that we are interested in is shown. The population that we are interested in is older adults, 65 years and older, at risk of developing or diagnosed with delirium. In addition, considering disparities in health care, we will encourage inclusion of underrepresented minority
populations in the PFA.

The interventions we're interested in are single and multicomponent interventions covering the spectrum of non-pharmacologic training guidelines, tele-health interventions as outlined. These interventions are at every level from the individual patients to systemic intervention.

The outcomes cover the different areas, taken into consideration core concepts prioritized by the field. These include delirium occurrence, inclusive of incidents being an outcome of interest in all of the areas, severity of delirium, time to resolution, stakeholders emphasized patient-centered outcomes, which such as health-related quality of life, patient discharge disposition, patient and/or caregiver distress, which are secondary outcomes of interest and outcomes that we have that are shown on the slides.

But in terms of timing, duration of studies that depend on the outcomes are variable, but it would be no longer than five years.

Overall, we are requesting a total
commitment of $30 million, depending on the applications received. These targeted funding announcement could be released for up to three cycles in order to fund up to three to five studies. with the maximum duration of up to five years.

Thank you. And I will hand over to Alicia for any discussion.

CHAIRPERSON GOERTZ: I'm going to take over it at this point. Thank you so much Yewanda, for that overview. I'd like to now open it up for discussion. Mike?

DR. HERNDON: I just need some education about the topic of delirium. Delirium seems in my vocabulary as a family practitioner seems very broad. But since we're talking about older adults, are we talking about dementia or are we talking about, you know, other medical illnesses other than dementia that can lead to delirium?

Can you kind of talk to me about what our aim is more specifically than kind of delirium, because to me, delirium is kind of broad in description.
DR. AKINBAMI: Thank you for that question. So we do realize that delirium is broad, but so we're interested and we do realize that delirium is multifactorial in our region. And so, that's why we have focused this topic on older adults, 65 years and older. And we will be interested in patients who have been diagnosed with either delirium or at-risk of delirium in medical settings and long-term care settings.

Part of the reason why we have also focused a little bit on this particular topic and in this population is because this is the population where we have the most in terms of evidence that is needed, that needs to be addressed for this particular topic.

I don't know if that addresses your question in terms of what we're focusing on delirium and the population.

DR. HERNDON: Yeah. I think in my experience, the most common cause of delirium in the adult population is medication induced, you know, medication reactions. So anyway, yeah, I just kind
of was wanting to focus and just get a little bit better understanding.

Alicia, do you --

DR. FERNANDEZ: Thank you very much for your question, Mike. So this is, as you correctly, point out an enormous topic, and I have to say, this is another area where I think the SOC did a really good job in working with the staff and the staff did a fantastic job in thinking through which piece of this, where is this right for comparative effectiveness research.

And this call is for comparative effectiveness research in a fairly -- still very broad, but not ridiculously broad area around delirium. So I feel very comfortable that this will yield actually really wonderful and highly applicable, highly important research results, because as you say, a lot of delirium, particularly in the hospital setting is intergenic, both by being hospitalized and of course by medication use and so on and so forth.

And so, we are looking for studies and
proposals that are poised for dissemination that focus on implementation challenges and that work within very defined settings. So thank you for this. And I, and we, and please know that the SOC discussed this at great length.

DR. HERNDON: Understood. I get it now.

Thank you.

CHAIRPERSON GOERTZ: Thank you for the question, Mike and Alicia for that clarification, that's really, that's really helpful.

Are there any other comments or questions at this point?

[No response.]

CHAIRPERSON GOERTZ: All right. And in that case, I am going to first of all, ask Rachel, are there any changes to the attendance?

MS. BARNES: No changes and we still have a quorum.

CHAIRPERSON GOERTZ: Great. Thank you so much.

All right. Do I have a motion to approve the development of the prevention, early
identification, and treatment of delirium targeted PFA with funding up to $30 million in total costs?

[Multiple speakers.]

CHAIRPERSON GOERTZ: All right, let's try that again.

DR. HERNDON: Mike, so moved.

CHAIRPERSON GOERTZ: Thank you, Mike. And can I get a second?

DR. RHODES: Karin, second.

CHAIRPERSON GOERTZ: Sorry who was that second?

DR. RHODES: Karin Rhodes, second.

CHAIRPERSON GOERTZ: Oh, thank you, Karin.

All right. Is there any further discussion?

[No response.]

CHAIRPERSON GOERTZ: I call for a voice vote then. All those in favor, please say aye.

[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[No response.]

CHAIRPERSON GOERTZ: Abstentions.
[No response.]

CHAIRPERSON GOERTZ: Okay. The motion passes. What I’d now like to do is ask the chair of our EDIC committee to present to us on an initiative that I’m particularly excited about the health systems implementation initiative. Mike.

DR. HERNDON: Thank you, Christine and I too, am excited to have this discussion.

So during this session we will be presenting on the new dissemination implementation program, an award program that’s entitled Health Systems Implementation Initiative or HSII. Through the HSII, PCORI will fund implementation projects that will be led by healthcare delivery systems and provider-affiliated networks.

And those of us who worked in those provider-affiliated networks, hospital, and provider networks, which was, you know, I had 15 years of practice in one. It makes a lot of sense for boots on the ground providers to be involved in these implementation strategies. So I'm very excited about this. These projects will take place directly
within the health care delivery systems in other words.

So at the EDIC November meeting, we had lots of discussion and actually talked about it at a couple of meetings. But we voted to recommend that the Board approved the proposed approval framework for HSII implementation projects and the commitment of funds for HSII.

And I did want to just give you know, some personal thoughts that I do think this is something that would be very attractive to large health systems, such as Kaiser Permanente and others, but also would be quite attractive to maybe some smaller health systems and networks such as the Sisters of Mercy System, which is, you know, Headquartered in St. Louis, but it has a larger presence with multiple hospitals and over 100 -- pardon me, a 100 clinics and facilities. So, you know, it has the reach to get just beyond the large usual suspects, if you will, for health systems, as research and implementation. But down to even some of those medium-sized where the rubber meets the road into
quotes with provider and patient engagement.

So at this point, I'd like to turn it over to Joanna Siegel to tell you more about this initiative and what we're recommending to the Board for approval today. Joanna.

DR. SIEGEL: Great. Thank you, Mike.

Next slide please.

So as it came up earlier today, at PCORI our goal is not just to do research, but to assure that the research we fund is used to assist patients, caregivers, clinicians, and others in informing their healthcare decisions. This commitment to uptake and use of evidence from our funded research is something that distinguishes us.

Traditionally, research funders have focused on publication as the end goal of research. Publication is of course a critical step, but at PCORI, we have an explicit commitment to steps beyond publication, including the prompt release of findings. And that is accessible plain language findings to the public. The active dissemination of findings to increase knowledge and awareness among
our target audiences who can use them.

And importantly, to the dissemination -- to
the implementation of findings, moving evidence from
the research context towards promoting uptake and
use in real world practice and decision-making
sessions.

Next slide, please.

So the focus of our presentation today is
on a new initiative we have in development in pre-
chorus D&I program to extend our work in that last
step implementation. As Mike said this new
initiative will allow us to provide funding directly
to healthcare delivery systems and provider
affiliated health plans as awardees to promote the
uptake of evidence within their healthcare delivery
settings.

HSII will complement our current funding
initiatives in D&I. These initiatives, three of
them, include both limited and open competition
opportunities and they focus on different evidence,
but what they all share is that they're led by
investigator teams. Most often researchers who have
a previous PCORI-funded research award or who've done related research. HSII will be different in that it will allow us to work directly with provider-affiliated health plans that have an important role in healthcare delivery and with healthcare delivery systems.

This approach offers us a number of important advantages, which you see listed here, including that HSII will allow us to engage the experience and the expertise within healthcare delivery systems and leverage their commitment and enthusiasm for adopting evidence-based practices. It'll allow us to take advantage of the opportunity to integrate implementation into health systems operations, facilitating efforts, to change practice, and also building towards sustainability.

And in addition, we expect that implementation activities through HSII will lay groundwork for future scale-up in other health systems by adapting and demonstrating pathways to uptake and towards documenting the impact of those efforts.
We also expect HSII to be a learning opportunity and to facilitate the transfer of learnings across healthcare systems. Next slide.

We started work on HSII in 2019. We paused it last year during COVID when health systems clearly had their attention elsewhere. And then we restarted it in 2021 with the first step being a request for information directed to healthcare delivery systems and provider-affiliated health plans.

This RFI launched in May. It basically described the initiative and the asked respondents for their views on a number of questions for us to use in developing the initiative. In June and October, we presented to the EDIC on the HSII award program. And in October, also on the response to the RFI from the community. At their November meeting, as Mike said, EDIC voted to recommend that the Board approve the proposed approval of framework for implementation projects under HSII and the commitment of funds.

So today, what we'd like to do is describe
the HSII award program and to request Board approval for those two elements, the approval framework for HSII implementation projects and a funding commitment for HSII. Next slide.

To start, I’d like to provide this overview of the structure of HSII, which has three components. The first step is that PCORI will recruit HSII participants. That is a stable or a pool of qualified health systems and provider-affiliated health plans to join the initiative. Applicants will be selected based on their commitment and capability to implement and sustain practice change, and their ability to achieve significant and diverse reach.

Immediately after their acceptance as HSII participants, these organizations will have the opportunity to apply for PCORI funding to undertake capacity building projects. The goal of this capacity building opportunity is to strengthen HSII participants’ ability to undertake implementation efforts essentially to help these participants build toward a successful experience.
These kinds of funds could go, for example, redesigning staff roles, developing advisory committees or building internal teams or enhancing data systems or tools.

The third step at the bottom is where we get to the implementation activities.

HSII participants will undertake implementation projects. Each one is designed to support the uptake of specific evidence into practice within their delivery system and to sustain that practice change. In these projects, participants will be able to adapt interventions for their local settings, draw on tailored and tested implementation strategies, and also do evaluation of changes in practice within their health systems.

Next slide.

HSII is intended to accomplish these goals on the road toward building to PCORI’s goal of moving evidence from research into real-world practice. These goals will be how we measure success and what our program evaluation will need to assess. We want to demonstrate feasible and
scalable approaches for integrating evidence into practice. That is we want the HSII participants to adapt and then use approaches that work for them in getting evidence into practice in their systems. They must be scalable approaches that have the potential to work beyond any specific implementation project environment. We want HSII to accomplish meaningful uptake in diverse healthcare delivery settings through the implementation projects. In order to show that an approach to implementation works, it has to actually accomplish the change in practice.

Finally, we want to initiate the scaling of successful implementation approaches beyond the HSII participants delivery systems. Although we should be able to achieve meaningful reach through HSII, we would not likely be able to accomplish comprehensive changes in practice at a national level. For that we'll want to work with others to support the further scale up of successful approaches.

Specifically, AHRQ has national reach, a mandate to conduct D&I of PCOR, an interest in
accomplishing broad scale implementation, building on successful implementation of evidence outside the research context.

Stakeholder organizations, such as professional societies and patient organizations, can also support ongoing scale-up of these approaches. Next slide.

Further, HSII will have the goal of accomplishing these objectives in diverse settings. We will seek HSII participants that have diverse patient reach, experience serving vulnerable populations, and close relationships with community partners, stakeholders, and patient communities. We'll also seek to include different types of healthcare delivery systems, including less resourced systems. We'll look for geographic diversity, systems serving different communities, and systems that don't typically engage with research funders.

Next slide.

Implementation projects will all conduct program evaluation in HSII, and it will examine
implementation process outcomes that document the completion of implementation activities, and also impacts on healthcare and health outcomes. These are the types of outcomes we assess in all the PCORI D&I projects. However, with HSII we'll have the additional opportunity to conduct the longer-term evaluation.

We'll ask HSII participants to assess sustainment of practice change in their health care systems. And we'll also look to capture uptake beyond these systems.

Final reporting on implementation projects will include reporting on achievements and impacts, but it will also include making publicly available the tools and materials developed during implementation projects to support future implementation. Next slide.

One final component of HSII that I'd like to note, is that we'll put in place a learning network for participants to support and facilitate their success in this initiative. The learning network will serve several purposes. It'll provide
a venue for participants to share experiences in planning and executing implementation efforts, and also in addressing challenges that will inevitably arise. It will provide resources and learning opportunities to support the participants. And importantly, it will provide an opportunity for HSII participants to weigh-in on the PCORI's proposed topics for implementation or suggest topics based on PCORI-funded research.

We expect that as a new initiative, a great deal of learning will take place. And the learning network will allow us to capture these learnings, use them to improve the HSII award program and also work towards sharing these experiences more widely.

Next slide please.

So at this point, I'd like to turn to the more specific focus of outlining the proposed approval framework for HSII.

First, these are the principles we use to guide the development of the review and approval process or framework for HSII. The Board of Governors and the EDIC have underlined the
importance of speed and efficiency in getting findings from research into practice. We also heard a lot about this from our RFI respondents. So this is a primary goal.

Transparency and fairness, always a goal of PCORI-funded initiatives. And one we are addressing through the use of existing PCORI review and approval structures, which have been developed to ensure community responsiveness. These existing structures include both procurement and merit review processes. To ensure rigor the approval process for HSII implementation projects will draw on input from external reviewers with subject matter expertise and maintain EDIC’s involvement and oversight.

Finally, approval processes within PCORI will emulate previously used Board approved processes to ensure appropriate levels of authority.

Next slide, please.

In the next couple of slides, I’m going to describe the approval framework for each of the three HSII steps. Starting with this step one, the selection of HSII participants to join the
initiative. Applicant organizations, these are the healthcare delivery systems and provider-affiliated health plans, will submit applications in response to an initial call for proposals to become HSII participants. Merit review and PCORI staff will be responsible for the review of these applications. The Executive Director or Designee will then consider and make decisions regarding the approval of applicants to join HSII.

Applicants selected will enter into master funding agreements or MFAs. Note that this step actually does not involve any funding from PCORI.

Next slide, please.

Step two is again, the step where HSII participants have the opportunity to apply for initial fundings to strengthen their ability to conduct successful implementation projects under HSII. So immediately after they're selected as HSII participants, they'll be able to propose projects in response to a call for HSII capacity building project proposals. Their proposed projects may have budgets up to $500,000.
PCORI staff and external experts will review the proposals and the Executive Director or Designee will make the funding decisions for slates of these awards. This approval process for the capacity building projects is quite similar to Board approved processes for the approval of small D&I awards that have similar budgets. And also for the engagement awards, both of which are approved by the Executive Director or Designee.

Next slide.

Step three. Again is where the implementation takes place in the HSII award program where the HSII participants are proposing the implementation projects to put findings generated from PCORI-funded research into practice.

To begin with HSII participant input, PCORI will identify the evidence focus for the implementation projects and issue topic-specific calls for implementation project proposals. HSII participants can respond to as many of these calls for proposals as they wish with the implementation projects being proposed having a budget of $1 to $5
million in a range from two to five years in length.

Next slide.

This slide shows the approval process for the implementation projects, which draws from PCORI’s recent experience with the COVID TPFA approval process. And I'll go through this in a little bit more detail since this is where the main funding will occur in the HSII award program.

So from left to right once the applications for implementation projects are submitted, PCORI staff and external experts will review the proposals against criteria that are designed to assure high quality implementation science-based implementation projects. The review criteria for these projects will be consistent with those that we use for current D&I awards, except that because the participants will have been pre-vetted through earlier merit review, we’ll have less need to review things like personnel qualifications, leadership buy-in, and some other of these important considerations.

The EDIC which serves as the selection

B&B REPORTERS
29999 W. Barrier Reef Boulevard
Lewes, DE  19958
[302] 947-9541
committee for the D&I awards program will then consider projects recommended by PCORI staff and recommend slates of awards to the Executive Director. The EDIC has significant experience in this role having served as the selection committee for the large D&I funding awards for the past several years for all three of the D&I programs funding initiatives.

The ED will make the funding decisions for the HSII awards, with the process that mirrors the one approved by the Board in May 2020 for the COVID TPFA, which had awards of a similar size, those being in the range of $2 to $5 million.

So specifically for the COVID TPFA, the Board authorized the Executive Director to approve COVID-19 TPFA award slates following a recommendation from the Selection Committee. And the proposed process for HSII draws on that model.

So this is the approval framework we're asking you to approve today, along with the commitment of funding for the HSII award program at the level of $15 million per fiscal year, beginning
this year, not to exceed a total of over $50 million over five years.

So at this point I will turn it back to you, Dr. Goertz for the motion before the Board. And I am happy to answer any questions.

CHAIRPERSON GOERTZ: Thank you so much, both Mike and Joanna. Is there any comments or questions. James?

DR. SCHUSTER: Yeah. Thank you. It looks like a really wonderful opportunity to engage systems who haven't been necessarily as engaged previous.

The one question I had was around the initial award of the $500,000 for capacity building, which seems modest if we really want the systems to work on capacity building. So I was wondering if you could say a little bit about the group's thoughts of that, and if there was any consideration about that number being a bit higher.

DR. SIEGEL: Sure. We thought a lot about that because we're expecting to have systems that obviously have different size and different current
capacity. And we asked this question explicitly in
the RFI in order to get kind of more feedback. We
did get, I think, 24 responses to the RFI. So we
got a good deal of input. And almost unanimously,
there was positive response to that.

What people told us was that you know, it
was likely that projects would be stepwise in any
case. And this initial support would be very
helpful in kind of plugging up some holes. It might
not build a full capacity for all systems.
Clearly, it's not at that level. But it would be a
good start and a good opportunity for people to
basically build strength where they need it.
So that's what we're hoping it'll be used for.

DR. SCHUSTER: Okay. Thanks.

DR. HERNDON: And James, I might just add
to that, you know, I think -- what you know, I
envisioned was, you know, most of these systems are
going to have their Chief Quality Officers.
And the Chief Quality Officer may be the one who
kind of oversees, you know, these efforts, you know.
But they're going to need support staff. Maybe the practice facilitator, you know, the person who goes out into the actual clinics to help.

And so, getting those kind of -- getting the person, the Chief Quality Officer, kind of that support staff and maybe that facilitator or two to actually, you know, do the education that's kind of -- and it made sense to me that you can ramp up with half a million dollars. You know, if you have an existing system that already has kind of that umbrella infrastructure in place.

DR. SCHUSTER: Okay, good. Thanks for the additional detail.

CHAIRPERSON GOERTZ: Any additional comments or questions?

[No response.]

CHAIRPERSON GOERTZ: All right. In that case, I am going to, first of all, ask Rachel, if there are any updates to the attendance?

MS. BARNES: Yes, thank you. Kate Berry and Connie Hwang have joined the meeting.

CHAIRPERSON GOERTZ: Thank you so much.
All right, I'm going to ask for a motion to approve the proposed framework for the HSII implementation projects, including PCORI staff reviews of proposals, the EDIC consideration of projects, and recommendation of slate of awards, and Executive Director consideration and approval of slate of awards.

In addition, we are looking for approval of a commitment of funding up to $15 million per fiscal year, beginning in FY 2022 to fund projects awarded under the health systems implementation initiative not to exceed a total of $50 million for five fiscal years.

DR. LEVINE: So moved. Sharon Levine.

CHAIRPERSON GOERTZ: Thank you, Sharon.

DR. FERNANDEZ: Second.

CHAIRPERSON GOERTZ: Okay. Alicia, thank you. Is there any further discussion?

[No response.]

CHAIRPERSON GOERTZ: All right. I'm going to ask for a voice vote then. All those in favor, please say aye.
[Ayes.]

CHAIRPERSON GOERTZ: Opposed?

[No response.]

CHAIRPERSON GOERTZ: Abstentions?

[No response.]

CHAIRPERSON GOERTZ: All right. Thank you.

DR. SIEGEL: Thanks very much.

CHAIRPERSON GOERTZ: Well, we have gotten a record amount of work done in a really quick time period -- we’re a little bit early. I don’t believe -- I want to confirm that we do not have anyone scheduled for public comment.

Can Nakela or Michelle or Kristin, please confirm that?

DR. CARMAN: That’s correct. No one has registered for public comment.

CHAIRPERSON GOERTZ: Okay. Well, in that case, I think we’re -- we’ll probably end a little bit early, but before we do so I’m going to turn it back to Nakela for some closing remarks.

DR. COOK: Thanks Christine. And what an exciting meeting, a rich meeting with lots of great
discussion, and I just wanted to appreciate the Board members for all the input on the many rich agenda items today and the feedback on things such as the Dashboard. And I heard a lot of great comments, including the importance of the work of the Strategic Planning committee and taking on some activity related to thinking about the evaluation and evaluation metrics that will serve us well as we move into our next phase under our new Strategic Plan.

I also heard importance of thinking about metrics that may help us with measuring progress in other areas in addition to our research, such as the activities that we engage with other stakeholders, and how we measure our effectiveness and those efforts and reaching those beyond the research committee.

I'm also really excited, as I think a lot of the staff at PCORI will be, to move forward toward the new targeted PFAs that were approved by the Board today, as well as the health systems implementation initiative. It's a really exciting
time for us. And I would be remiss if I didn't say
congratulations to all the awardees for the slates
that were approved today. And we will continue to
do our work to fulfill next year's Commitment Plan
targets and look forward to moving all these items
forward to do so.

Lastly, I would ask that all Board members
and our stakeholders that are tuning in, please look
out for the posting of the proposed research agenda.
We look forward to hearing comments during the
public comment period, which will stretch from
December through January.

And I believe those are all of the exciting
things from today and we look forward to continuing
the work with the Board in the new year as this
would close out our meetings for the year.

CHAIRPERSON GOERTZ: Thank you so much,
Nakela. I really, really appreciate all of the work
-- thanks to you and the staff for all of the work
that went into a planning of this very rich meeting.
Thank you to Board members for hanging in with us
over two full days. We are -- just a reminder that
you're not quite done yet. We are going to be engaging in a planning session that will start in -- why don't we start that at 3:30 Eastern time. So in just a few minutes.

But I do want to thank all of you who joined us via webinar and teleconference.

Congratulations to our new investigators. We really appreciate your commitment to PCORI and look forward to seeing the results of your studies available. A reminder that all of the materials that were presented to the Board today will soon be available on our website.

Today's webinar was recorded and the archived webinar will be available in about a week or so. As always, we recommend your feedback at info@PCORI.org or through our website at www.PCORI.org.

Thanks again for joining us and have a terrific afternoon.

Take care.

[Whereupon, at 3:11 p.m. EST, the Board of Governors meeting was adjourned.]