

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

BOARD OF GOVERNORS MEETING

11:30 a.m. EST

Thursday, December 2, 2021

Webinar

[Transcribed from the PCORI webinar.]

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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

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P R O C E E D I N G S

[11:31 a.m. EST]

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

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1 on a matter that represents a conflict of interest
2 for you, please recuse yourself or inform me if you
3 have any questions.

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

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

11 Rachel, would you please call roll?

12 MS. BARNES: Yes. Kara Ayers.

13 DR. AYERS: Present.

14 MS. BARNES: Kate Berry.

15 MS. BERRY: Present.

16 MS. BARNES: Tanisha Carino.

17 [No response.]

18 MS. BARNES: Francis Collins or Michael
19 Lauer, Designee of the NIH Director.

20 [No response.]

21 MS. BARNES: Jennifer DeVoe.

22 DR. DeVOE: Present.

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1 MS. BARNES: Alicia Fernandez.
2 DR. FERNANDEZ: Present.
3 MS. BARNES: Christopher Friese.
4 [No response.]
5 MS. BARNES: Christine Goertz.
6 CHAIRPERSON GOERTZ: Present.
7 MS. BARNES: Mike Herndon.
8 DR. HERNDON: Present.
9 MS. BARNES: Russell Howerton.
10 DR. HOWERTON: Present.
11 MS. BARNES: James Huffman.
12 MR. HUFFMAN: Present.
13 MS. BARNES: Connie Hwang.
14 DR. HWANG: Present.
15 MS. BARNES: Sharon Levine.
16 DR. LEVINE: Present.
17 MS. BARNES: Michelle McMurry-Heath.
18 [No response.]
19 MS. BARNES: Barbara McNeil.
20 [No response.]
21 MS. BARNES: David Meyers or Karin Rhodes,
22 Designee of the AHRQ Director.

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1 DR. RHODES: Karin Rhodes is here.

2 MS. BARNES: Eboni Price-Haywood.

3 [No response.]

4 MS. BARNES: James Schuster.

5 DR. SCHUSTER: Present.

6 MS. BARNES: Ellen Sigal.

7 [No response.]

8 MS. BARNES: Kathleen Troeger.

9 MS. TROEGER: Present.

10 MS. BARNES: Daniel van Leeuwen.

11 MR. VAN LEEUWEN: Present.

12 MS. BARNES: Janet Woodcock.

13 [No response.]

14 MS. BARNES: Robert Zwolak.

15 [No response.]

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

17 CHAIRPERSON GOERTZ: Thank you so much.

18 Can we have the next slide please?

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

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1 annual review at the end of the year.

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

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

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

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

20 Okay. The two items on the Consent Agenda
21 then are the meetings from our October 26th, 2021
22 Board meeting, and also the nomination of Cristina

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1 Murray-Krezan as a member of the Advisory Panel on
2 Clinical Trials to serve a three-year term. So
3 starting now and through August of 2024, or until a
4 successor is appointed because this is a replacement
5 appointment. She has been recommended for Board
6 approval by the Methodology Committee. Her
7 stakeholder group is that of a researcher, she's a
8 statistician, and she is at the University of
9 Pittsburgh.

10 Next slide please.

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

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

15 DR. LEVINE: Sharon Levine, second.

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

18 [No response.]

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

21 [Ayes.]

22 CHAIRPERSON GOERTZ: Opposed?

1 [No response.]

2 CHAIRPERSON GOERTZ: Abstentions?

3 [No response.]

4 CHAIRPERSON GOERTZ: Okay. Thank you.

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

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

20 And he has -- that those efforts really
21 were instrumental in helping to demonstrate to
22 Congress the value of -- that PCORI brings to our

1 nation, leading to our 10-year reauthorization.
2 So we owe a great debt of gratitude to Andrew and
3 Andrew do you mind putting your camera on for a
4 second?

5 MR. HU: Okay.

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

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

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

1 you so much. Take care.

2 MS. HU: Bye.

3 CHAIRPERSON GOERTZ: Bye-bye.

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

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

12 Let's go to our next slide.

13 So we'll kick it off with our fiscal year
14 2021 Dashboard review. And here you see the
15 snapshot of our Dashboard with several of those
16 quantitative measures that really lend themselves
17 well to encapsulated reporting and they're
18 represented here with increasing measures of impact.
19 If you look along the left of the slide here, you'll
20 see inputs from, or you'll see measures from inputs
21 increasing toward use and as you progress down this
22 slide.

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1 And the Dashboard, actually something that
2 continues to evolve. And from this focus that was
3 primarily on inputs in our early days to process.
4 And now our progress on our goals, our output and
5 uptake. And we're looking ahead to our measurements
6 of impacts as we continue to move forward with our
7 Strategic Plan and subsequently evolve our Dashboard
8 to those priorities.

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

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

21 And then finally at the bottom of the
22 slide, you can see uptake in use metrics on that

1 last row. And we have things there such as uptake
2 into patient and public resources, uptake of results
3 into a clinical decision tool called UptoDate, as
4 well as other examples of uptake.

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

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

21 And you can see here that 100 percent are
22 within the 90-day limit. And that's something

1 that's really important from our authorizing
2 legislation. And our average in terms of our time
3 to release of research findings is about 86 days.

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

16 We can go ahead to our next slide.

17 So here, I wanted to spend a little bit of
18 time on the status of PCORI-funded research
19 projects. And here you can see the percentage of
20 projects that are on track in the green or yellow
21 zones, and those that are off-track in the red. And
22 the last 12 quarters are reported here. And

1 overall, for the most part, PCORI-funded projects
2 are on track and our green color-coded ones are
3 those that are highly to meet the objectives as
4 planned. And you can see that 60 percent of our
5 projects fall in this range, with a slightly lower
6 number in the last quarter here as compared to prior
7 quarters, and more that have kind of shifted into
8 that yellow zone, which we think is related to some
9 of our COVID-19 implications on our portfolio.

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

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

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

22 So at the end of the fiscal year, 2021, we

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

7 Let's go to the next slide.

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

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

22 We also know that through our evaluation,

1 that the most common cause of a delay is a
2 significant decrease in recruitment in other study
3 activities. And that's about three quarters of
4 those that fall into that zone.

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

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

1 on the research enterprise in general. And this is
2 generally what we're seeing across other funders as
3 well. But we certainly have also seen a decrease in
4 researcher productivity during the pandemic and as
5 well as increased stress on mental health for
6 researchers, and a differential effect on women and
7 parents of young children and people of color, and
8 that are really affected by pandemic-related
9 disruptions and need more support.

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

14 Let's go to the next slide.

15 So PCORnet also has metrics that are
16 tracked on our Dashboard and has been a source of
17 ongoing contributions to a lot of the COVID-19 work
18 that's been funded by the PCORI and others. And
19 while you don't see PCORnet on the overall snapshot
20 Dashboard, it has its own metrics and issues that
21 are raised to the Board as appropriate. And we now
22 have the PCORnet Dashboard available on PCORI's

1 website for full transparency. And you can see that
2 it includes about 13 metrics monitoring things like
3 Front Door requests, COVID-19 projects, data
4 quality, publications, and resource utilization, and
5 funded studies.

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

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

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1 You can go to the next slide.

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

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

21 There's also a lot of data on attention to
22 our results pages. And what we found is that

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1 downloads of final research report average about
2 1,500 per quarter last year, and for research
3 results pages we find that there are a lot of unique
4 visitors to our research results pages. And this
5 can average somewhere like 19,000 to 20,000 per
6 quarter last year. So this is a really, I think,
7 robust resource for the public to find information
8 about the PCORI's funded studies.

9 Let's go to the next slide.

10 So I did want to talk a little bit about
11 attention and the attention that this studies from
12 the PCORI-funded portfolio actually receive. And
13 the results that are being posted on our website are
14 not just results of what we funded, but they're
15 actually very noteworthy and are garnering
16 attention. So PCORI-funded investigators derived
17 multiple publications per funded project with over
18 3,000 publications resulting from PCORI-funded
19 studies thus far and of these over 2,000 are with
20 empirical results. And about 400 of these are
21 primary or secondary CER results.

22 So here we see the attention to these

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1 results publications as measured by Altmetric
2 scores. And so, on the left side you see that a lot
3 of our publications from PCORI-funded studies have
4 high Altmetric scores, greater than 20, but on the
5 right, you can see that on average 13 percent of CER
6 results publications exceeded the target of greater
7 than 10 percent of results publications garnering
8 the top 10 percent attention in the relative
9 journal.

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

12 And this slide just gives you an example of
13 highlights of attention to six PCORI CER results,
14 publications as measured by Altmetric scores of
15 greater than a hundred. These are really high
16 scoring CER results publications from fiscal year
17 2021. And the score indicates attention in news
18 articles or on social media blogs and in other types
19 of blogs.

20 And so of note, you'll see the first study
21 here is one that compared antibiotics with
22 appendectomy for appendicitis and is of the top 11

1 percent for an Altmetric score for articles that
2 were published in the *New England Journal of*
3 *Medicine*.

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

11 And the third one is around an "Association
12 Between Gender-Affirming Surgeries and Mental Health
13 Outcomes," and is among the top three percent of
14 attention in *JAMA Surgery*.

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

21 So these are just from fiscal year 2021,
22 but you can see here that journals like the *New*

1 *England Journal of Medicine* and *JAMA* tend to have
2 higher Altmetric scores. And this is just a
3 snapshot of some of those higher attention-grabbing
4 studies that have been published from the PCORI-
5 funded studies.

6 We can go ahead to the next slide.

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

19 And nearly all of these individuals are
20 going to need surgery with anesthesia. So this
21 study actually compared how general anesthesia
22 versus spinal anesthesia affected recovery and long-

1 term health in about 1,600 patients that were over
2 the age of 50 and scheduled to have surgery for hip
3 fracture, and found that really spinal anesthesia
4 for hip fracture surgery in older adults was not
5 superior to general anesthesia with respect to
6 survival, as well as the ability to walk two months
7 after surgery. And both forms of anesthesia were
8 equally safe.

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

21 Let's go to our next slide.

22 So continuing on that trend of really our

1 outputs and I wanted to take a look here with you at
2 the public availability of our primary CER results.
3 And as you can see here as of Quarter 4 of 2021, 388
4 PCORI-funded studies have primary CER results, peer-
5 reviewed and publicly available. And this number
6 had been steadily increasing and continues to
7 increase.

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

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

19 So this slide actually demonstrates the
20 percentage of CER results that are available by
21 publication relative to the primary completion date
22 of the clinical trial. From what you can see here

1 is that the research results from PCORI-funded
2 studies and the blue dashed line published in the
3 peer-reviewed literature at a similar rate, or
4 really better even than the benchmark, which is in
5 the orange line. Let's look at the next slide.

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

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

21 And so, I finally want to bring it all
22 together and here you can see the difference that

1 the PCORI peer review and posting of abstracts
2 makes. PCORI's process provides complete and
3 earlier availability to the public of research
4 results from PCORI-funded CER studies over and above
5 the publications alone. And PCORI-funded
6 investigators are not hampered in publishing by
7 going through this peer review process, the blue and
8 orange curves are really similar as you can see
9 here, and then they depart.

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

14 So I just want to shift gears and focus a
15 little bit on uptake measures of results from PCORI-
16 funded studies on the path to implementation. And
17 so, here you see uptake in evidence-based clinical
18 recommendations and we'll start with UpToDate, one
19 of those clinical decision tools, and you can see
20 our provisional target based on historical data is
21 to have about 28 results taken up into UpToDate per
22 year. And at the end of the year, there were 32

1 citations of CER results in UpToDate and 98 that are
2 cumulative to date, and you can also see citations
3 and other clinical recommendations with 20 this
4 year, this fiscal year and the cumulative of 74 to
5 date.

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

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

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

1 two UpToDate clinical topic pages.

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

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

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

18 Let's go to the next slide.

19 So I just wanted to pause here and invite
20 some discussion on the Dashboard before I come back
21 and tell you a little bit more about highlights from
22 the year in review.

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1 So we're really interested in hearing
2 whether our fiscal year 2021 Dashboard and a lot of
3 the background materials cover the topics that are
4 most important for you to review and whether or not
5 you have questions or comments about performance on
6 any of these Dashboard indicators. And as we move
7 forward in developing our Strategic Plan, it'd be
8 really helpful to hear the role and content you
9 envision for the Dashboard in measuring progress and
10 measuring success, because this actually can be a
11 component of us in terms of our thinking about our
12 Strategic Plan is how we want to evaluate it moving
13 forward and how we leverage this Dashboard to help
14 us do that.

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

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

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

21 How do we use the Altmetric scores and the
22 information gained from these Dashboards about the

1 utility of our studies to drive our topics for study
2 selection.

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

7 DR. HERNDON: Exactly, yes.

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

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

22 And so, it's probably not as formal as

1 processes you may be describing, but it is part of
2 what we do take into account in terms of how we
3 digest where we've been and think about what we
4 could be doing in our next steps. And those are
5 some robust discussions that happen PCORI-wide on a
6 regular basis.

7 DR. HERNDON: Thank you.

8 CHAIRPERSON GOERTZ: Thank you. Danny.

9 MR. VAN LEEUWEN: Yes, thanks for this
10 report Nakela. I want to make several comments.

11 The first one is this what we mean by a
12 public available data -- or results. And the first
13 is I think when you say public you mean research
14 industry because most of what you've shared in terms
15 of the Dashboard. And so, for those that are
16 research industry you know, so peer-reviewed
17 journals and the like, I'm wondering about the pay
18 wall. And you know, what is all of these really
19 public and that term?

20 I also think that, like, when I think about
21 public, I think about non-research industry
22 available material and about PCORI and its results.

1 And I think it's not just about the study results,
2 but it's about PCORI itself about strategy, about
3 equity, about community and patient engagement,
4 about our priorities. And I'm wondering how we are
5 orienting ourselves and measuring the sort of the
6 non-research industry and the non-results part of
7 what we do, which is really considerable and which
8 the public might actually have considerable interest
9 in.

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

17 So everything is translated into lay
18 abstracts on our website, but we also have started
19 to look for our ability to have uptake in different
20 venues. And some of that actually came from, I
21 think, a comment you made earlier when we reviewed
22 the Dashboard maybe at mid-year or last December,

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1 where we started to then track to see the uptake and
2 how our results are getting uptake and into some of
3 the more lay-friendly venues. And I mentioned blogs
4 and other types of sources that were looking at now.

5 The last thing that I did want to say,
6 though, is I liked your comment about beyond the
7 research results and how we track our effectiveness
8 around other types of activities that PCORI is
9 engaged in. And we can think about that a little
10 bit more together in terms of how that may be
11 possible. We do try to make sure that we have that
12 information available on our website, but tracking
13 the effectiveness of it, in many ways I'm not as
14 sure that we've figured out ways to do that.

15 MR. VAN LEEUWEN: Yeah. And I think the
16 part of the uptake is that other people -- so it's
17 not just you know, maybe people get directed to the
18 PCORI website, which is rich, but that is not
19 necessarily the original place or the first place
20 that people would go. And so, it's the encouraging.

21 So like in my work as a podcaster, I try
22 to, you know, highlight what's happening with PCORI

1 and then refer back to the website. And I'm just
2 wondering how we can encourage other people who are
3 more and more interested in what PCORI is doing,
4 especially in community and patient engagement.

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

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

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

1 and our struggle.

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

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

20 And in fact, as we're starting to develop
21 more and more of these ad hoc committees, like our
22 PCORnet Committee, for instance, is it possible to

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1 have those groups start to think about what sort of
2 things should end up on our Dashboard relative to
3 the work that the group is -- that the work that the
4 group is doing and perhaps to make some
5 recommendations to the Board about what benchmarks
6 we may want to consider in those particular areas.

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

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

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

19 CHAIRPERSON GOERTZ: Mm-hmm.

20 DR. COOK: Yes. And actually it's in my
21 next presentation, I was going to give a little
22 update about the fact that our website has actually

1 been revamped on a new platform that's going to
2 allow us even to do some of those measures and
3 metrics in terms of traffic to the site, even more
4 robustly. So this is something that our
5 communications team does track and we'll be able to
6 continue to track moving forward.

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

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

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

19 And now I wanted to go to Sharon. What are
20 your thoughts about asking the Strategic Planning
21 Committee to start thinking about how we might --
22 what we might want to add to our Dashboard?

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1 DR. LEVINE: I think there are two parts to
2 it. One is, do we -- or how do we reorganize the
3 Dashboard so that whatever metrics we choose to
4 follow, and I suspect they will evolve and change
5 over time, fit clearly -- have line of sight with
6 the strategic priorities that we've established with
7 the national priorities and with the research
8 agenda.

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

17 And I think we're at a point now with the
18 national priorities and soon with the research
19 agenda to say, okay, let's start with the bigger
20 picture of what our priorities are and then ensure
21 that the metrics we're tracking enable us to follow
22 our progress toward achieving national priorities

1 through funding research that fits with and is
2 aligned with the national priorities.

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

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

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

12 DR. COOK: Yes.

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

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

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

1 to close out another calendar year.

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

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

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

20 Let's go to our next slide.

21 So I just also wanted to highlight for our
22 Board members that earlier this month PCORI launched

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1 a new and redesigned website, and we were just
2 making reference to that in our last conversation.
3 And you'll immediately notice that the updated
4 website has a different look and feel, but the
5 website has also undergone more than just a cosmetic
6 make-over and the website's been moved on to a new
7 platform with a robust and sustainable technology
8 foundation and has improved infrastructure.

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

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

19 So if you haven't visited the new website,
20 please take a moment to do so and peruse all the
21 improvements. I think that it's going to be a
22 really important tool for our stakeholders to better

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1 access all the critical information that they're
2 looking for. Let's go to our next slide.

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

18 So every page of this report showcases the
19 work and commitment and accomplishments from all of
20 our Board members and staff. And so, hopefully you
21 all received your copy of this now award-winning
22 report and what an exciting accomplishment in this

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1 year.

2 Let's go to the next slide.

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

12 We had over 3,700 registrants and over
13 2,100 attendees for our Annual Meeting. And the
14 average attendee lingered. They didn't just come
15 and leave. Attending about 16 sessions and almost
16 six hours of content.

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

20 We can go to the next slide.

21 So over the past year, we focused our
22 efforts on both on what we do at PCORI and how we

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1 work, and what we do really relates to the
2 fulfillment of our mission. And we focused
3 attention, as well, on the collaboration and
4 teamwork and diversity equity and inclusion
5 principles has critical pillars of how we work to
6 accelerate fulfillment of our mission.

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

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

22 Our funding approaches included building

1 and implementing our COVID-19 response and executing
2 our PFA programming and alignment with our
3 Commitment Plan and implementing some rapid funding
4 approaches. Let's go to the next slide.

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

13 The Board has also worked with PCORI staff
14 and identifying those principals for the next phase
15 of PCORnet. And we talked about those earlier in
16 the year and it guided the solicitation of the Phase
17 3 PCORnet Clinical Research Networks and
18 Coordinating Center awards.

19 And last December, we also focused on our
20 Commitment Plan and had the first 3-year Commitment
21 Plan approved by the PCORI Board of Governors.
22 Really taking into account different scenarios and

1 then landing in a place that would move us forward.
2 And I'll be talking more about that and a little bit
3 later today.

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

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

22 Let's go to the next slide.

1 So this year we also marked progress on our
2 priority research areas in our reauthorizing
3 legislation. We began with engagement of
4 stakeholders, new and existing and diverse groups,
5 as well as those with lived experience in
6 interviews, webinars, workshops, and the like on
7 priorities of maternal morbidity and mortality, as
8 well as intellectual and developmental disabilities.

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

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

21 So our first efforts are listed here on the
22 right side of this slide, and they related to

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1 expediting a few funding announcements based on our
2 early stakeholder input. Our first effort was the
3 embedding of special areas of emphasis in our broad
4 announcements, but set aside funding. We had a
5 focus on patient-centered maternal care and improved
6 care for individuals with intellectual and
7 developmental disabilities growing into adults.

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

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

18 We also focused and made significant
19 progress this year on the provision in our
20 reauthorizing legislation to consider the full range
21 of outcomes data and PCORI-funded research. And in
22 a deliberate and stakeholder engaged approach for

1 PCORI, developed four key principles to guide our
2 approach and responded to public comment. And they
3 were approved by the Board in March of this year.

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

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

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

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1 Let's go to the next slide.

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

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

16 A substantial component to fulfilling our
17 mission is in our 3-year Commitment Plan and the
18 Board discussed several different scenarios back in
19 December of last year and approved a 3-year
20 Commitment Plan moving forward. And that's the
21 scenario that's presented here, but the major
22 accomplishment over fiscal year 2021 was meeting the

1 target for the fiscal year 2021 of \$482 million in
2 commitments.

3 Let's go to our next slide.

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

18 Next slide.

19 So I'm going to just spend a moment here to
20 mention that this year we've also taken attention to
21 the language in our reauthorizing legislation that
22 emphasizes a focus on both short- and long-term

1 activities, producing an array of evidence products
2 that are on the side of shorter term, as well as
3 longer term results.

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

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

21 And our newest effort, which represented a
22 significant achievement for PCORI is the Phased

1 trial or PLACER initiative, which funds that new
2 form of large pragmatic clinical trials. And the
3 PLACER announcement just yielded amazing results
4 this year or in fiscal year 2021.

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

8 Let's go to the next slide.

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

18 And this map was recently published on our
19 website. It's an interactive map and it captures
20 study results and it's regularly updated with new
21 data, allowing a user on the site to find the
22 studies where an intervention has shown some

1 benefit, as well as to see where there could be
2 evidence gaps, which also could actually help us
3 generate new research topics.

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

14 Let's go the next slide.

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

22 And these resources provide training in

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1 ways that allow individuals to learn about the
2 health research process and how to be involved in
3 patient-centered outcomes research, as well as the
4 importance of research team members working together
5 and understanding how to bring stakeholders into the
6 active members of the team and establish clear roles
7 and responsibilities that are needed to help
8 successfully complete a stakeholder-engaged research
9 project. Next slide.

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

20 Let's go to the next slide.

21 So how we work is just as critical as
22 fulfilling our mission because it enables us to

1 fulfill the mission. And teamwork and collaboration
2 is one component of how we work and this relates to
3 setting our PCORI culture and thinking about our
4 workforce and our workplace, as well as the
5 organization transformation work that we're
6 undergoing related to developing PCORI Next, our
7 structure for the future.

8 Let's go to the next slide.

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

18 Let's go the next slide.

19 And a key support to PCORI Next is a
20 corollary effort to consolidate our space and
21 support a collaboration and teamwork in a more
22 integrated approach and pursuit of our mission. And

1 we are pleased to say publicly that PCORI's new
2 offices will be at 1333 New Hampshire Avenue, and we
3 anticipate being able to move there in the summer of
4 2022. This has been a remarkable effort over the
5 past year and will be continued to be an important
6 focus for us in fiscal year 2022.

7 Let's go to the next slide.

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

18 And related to this, another major
19 accomplishment was the bringing together of the
20 PCORI and thinking about the main goals of a
21 diversity, equity, and inclusion strategy around the
22 three areas: learn, expand, and engage. And they

1 correspond to for PCORI's roles as an organization,
2 a funder, and a partner.

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

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

21 We also have a focus on a health equity
22 portfolio that will be stemming from that national

1 priority and a planned initiative that will come
2 before the Board in a future cycle.

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

15 So if we look forward into 2022, it's going
16 to continue to build on all these substantial
17 achievements in 2021. And as we look to fulfill our
18 mission, we are anticipating that together with the
19 Board will be able to adopt a Strategic Plan in the
20 summer of 2022. And that we will start to embark on
21 a new year in our Commitment Plan. And that year
22 will be the beginning of the peak of that plan with

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1 that front load of commitments that the Board was
2 really interested in seeing at PCORI.

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

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

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

21 CHAIRPERSON GOERTZ: Thank you so much,
22 Nakela. I just want to congratulate you and your

1 entire team for the tremendous effort that this
2 presentation represents. I wish we had time to
3 spend the entire day just going into much of this
4 work in more detail, but thank you and please convey
5 that our gratitude to your entire team for the
6 incredible amount of work that this represents.

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

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

11 [No response.]

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

15 DR. COOK: Fantastic. Well, today we're
16 also going to revisit our Commitment Planning for
17 the future. And as I mentioned last December, the
18 Board approved our 3-year Commitment Plan, aligned
19 to some really ambitious goals. And we've also
20 began to track progress toward our commitment
21 targets on a regular basis with the Board and place
22 our commitments in context with each cycle, when we

1 review our slates for awards. So hopefully that's
2 kept you up to speed on where we are with our
3 Commitment Plans, but I'll do a little refresher and
4 then talk about the proposed Commitment Plan for the
5 next three years.

6 Let's go to the next slide.

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

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

19 The steady state period that you see off to
20 the right has this range of approximately \$340 to
21 \$440 million per year, which accounts for basically
22 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

1 percent increase in staffing to support this
2 Commitment Plan. And this is still in process,
3 we're still recruiting. And as many of you know,
4 it's quite a competitive marketplace. And so, we
5 anticipate still needing that level of recruitment
6 to fulfill even next year's commitments.

7 Let's go to the next slide.

8 So the big update is that in fiscal year
9 2021, as I've said before, we met the ambitious
10 target, right? Of \$482 million. And here you can
11 see that the plan target in the column that's is
12 labeled fiscal year 2021 Target was 482. And then
13 the second column, you see the cumulative fiscal
14 year 2021 commitment across the different funding
15 categories with all the approved slates. And that
16 was about \$495 million or the actual commitments.

17 So we were about \$13 million above the
18 target and exceeding the target in this scenario
19 really did represent a strong suite of PCORI funding
20 announcements and applications and awards in fiscal
21 year 2021. And as I mentioned, our PLACER
22 solicitation really was a strong driver of some of

1 those awards.

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

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

19 Infrastructure as well was largely under,
20 due to a shift in timing of the PCORnet Coordinating
21 Center awards. There was about \$18 million that was
22 programmed for fiscal year 2021 that has shifted to

1 fiscal year 2022 to accommodate solicitation
2 timelines. And under commitments and new initiative
3 funds, were really used to try to pick up or fund
4 those larger than anticipated first slate of PLACER
5 awards that we talked about and other robust
6 research award slates. So that's how we were still
7 able to make the target for fiscal year 2021 and
8 anticipate as we move into 2022, that we'll have
9 those commitments that I talked about that shifted
10 into 2022 coming into fruition.

11 Let's go to the next slide.

12 So today the Board is actually considering
13 the proposed 3-year Commitment Plan for fiscal year
14 2022 to 2024. And really the upcoming fiscal year
15 2021 cycles of awards are going to be represented in
16 that Commitment Plan in 2022. And this is our first
17 year of that peak funding in the model of trying to
18 get to that \$600 million in commitments.

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

21 So the research category here represents
22 half-investigator initiated and half-PCORI priority

1 topics, via special areas of emphasis or targeted
2 funding announcements. It also includes the full
3 range of the research spectrum, including
4 dissemination research, as well as methods research
5 and some of those short- and long-term priorities
6 products that we talked about.

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

18 We do anticipate that as we're seeing these
19 results coming to fruition, that we're going to have
20 about twice as many results that are worthy of
21 implementation awards in the next few years from
22 larger investments that we've seen in the past and

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1 things like our PCS PFA and our targeted topics.

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

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

18 And this line does represent an increase in
19 engagement funding for more awards to support that
20 higher level of research and D&I commitments. And
21 as it relates to the commitments for PCORnet
22 infrastructure, they're limited here. The funding

1 that's placeholdered is for the Coordinating Center,
2 which was shifted from fiscal year 2021, as well as
3 funds to fill emerging gaps or issues related to the
4 current awards.

5 Originally, as I mentioned, there was about
6 \$16 million in 2022 for a PCORnet expansion or gap
7 filling. But when you add in the \$18 million, that
8 shifted for the Coordinating Center, it's part of
9 what you see here in this Commitment Plan.

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

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

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

21 So there are going to be several
22 principles that will guide our efforts to align with

1 the Commitment Plan targets and goals that you see
2 here. We'll continue with that accountability and
3 visibility and our progress toward our Commitment
4 Plan and goals at each cycle. We will have to make
5 sure that we're thinking about the prospective
6 planning of our PCORI funding announcements for our
7 full fiscal year or even multi-year in a way that
8 will help us to make sure we're planning to meet the
9 targets. And this was a very successful effort last
10 year. And we'd like to set that up again for the
11 coming year.

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

1 staffing increase for these key award activities.

2 So the item for approval today is this
3 slide, the 3-year Commitment Plan for fiscal year
4 2022 to 2024 subject to an annual review and update
5 by the Board similar to the way we're doing today.

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

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

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

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

1 becoming a priority, you know, it's gotten to the
2 level of a priority.

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

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

15 So if that helps a little bit with
16 timeframes, you know, the things that we're thinking
17 about now with our strategic priorities may shift
18 some things down the line. And so, we'd want to
19 start to build that into the annual review, but what
20 you're seeing for fiscal year 2022, now, really
21 reflects a lot of the things that are happening in
22 2021.

1 MR. VAN LEEUWEN: Thank you. That's been
2 helpful.

3 DR. COOK: Sure.

4 CHAIRPERSON GOERTZ: All right. Connie,
5 then Mike.

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

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

19 So you know, I'd love to hear from you in
20 terms of where can we as the Board be very helpful
21 in the years ahead to really help ramp that up. I
22 know, I think we'll be hearing a little bit more

1 about the health systems implementation initiative,
2 but more broadly, like for that particular category,
3 I'd just love to get a sense of, you know, where you
4 think the greatest challenges and opportunities
5 might be. Since it seems to be the one that's a
6 little bit sort of lagging a little bit in terms of
7 the funds spent.

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

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

1 dissemination and implementation.

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

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

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

22 So perhaps one of the things that could be

1 helpful for the Board to see is how across those
2 lines, the commitments are lining up. And we may be
3 able to do that for you in the future.

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

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

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

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

18 A couple of the things I want to comment.
19 It is so nice to see that we're meeting our
20 commitments. I mean, you know, for the last several
21 years we've been falling short of that and I'm
22 really delighted to see that we're actually above

1 some of the commitment, you know, over the last year
2 or two. So that's awesome and great to see.

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

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

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

21 And I just wanted to say that you have at
22 least my full commitment to get the right people in

1 the right seats and enough of them to do the job,
2 because this is important work. Thanks.

3 DR. COOK: Thanks for that comment Mike.

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

12 CHAIRPERSON GOERTZ: Thank you, Sharon.

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

21 And I know that that's been part of the
22 part of the language, but I just wonder if in our

1 effort to ramp up the implementable results, if you
2 will, if we couldn't look at the language of the
3 funding announcements and see if there isn't a way
4 to emphasize that, you know, we're looking for
5 impact and we're looking for results that have the
6 potential to have an impact through uptake and
7 implementation.

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

14 CHAIRPERSON GOERTZ: Great. Thank you.

15 Any other comments or questions for Nakela
16 on this particular agenda item before we vote?

17 [No response.]

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

21 MS. BARNES: Yes, Robert Zwolak has since
22 joined the call and we still have a quorum.

1 CHAIRPERSON GOERTZ: Great. Thank you so
2 much. And in that case, I'm going to ask for a
3 motion to approve the proposed 3-year Commitment
4 Plan for FY 2022 through 2024 subject to annual
5 review and update by the Board.

6 DR. HERNDON: Mike, so moved.

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

9 DR. RHODES: Second, Karin Rhodes.

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

12 [No response.]

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

16 So all those in favor, please say aye.

17 [Ayes.]

18 CHAIRPERSON GOERTZ: Opposed?

19 [No response.]

20 CHAIRPERSON GOERTZ: Abstentions?

21 [No response.]

22 CHAIRPERSON GOERTZ: All right. Thank you.

1 We have, we have a Commitment Plan for the next
2 three years. Thanks everyone.

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

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

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

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

1 research agenda.

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

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

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

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

17 You may recall that we discussed in our
18 prior meeting on the research agenda essentially the
19 development process and the timeline and what we'd
20 hoped to accomplish when we made it to our December
21 Board meeting. So today what we're going to do is
22 review the proposed research agenda that's been

1 revised as Sharon mentioned, and ask that you
2 consider for approval the proposed research agenda
3 for posting for public comment and to support this,
4 I'm going to go over a review of the revisions to
5 the research agenda that were made based off of the
6 Board's discussion during the October meeting a
7 couple of months ago. And I'll also share with you
8 a quick overview of some of the anticipated next
9 steps for the research agenda following today's
10 meeting.

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

17 Let's go to the next slide.

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

1 agenda.

2 Let's go to the next slide.

3 So I wanted to come back to this diagram.

4 It's one that you've seen before. It's the diagram
5 of the components of our Strategic Plan. And it
6 just helps, I think, in grounding some of the
7 conversations for today.

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

17 And the other component here is that the
18 research agenda help guides the development of a
19 continuously relevant research project agenda, which
20 is derived from an ongoing stakeholder engagement
21 process. And the research project agenda is where
22 the specific topics resides, such as intellectual

1 and developmental disabilities or maternal morbidity
2 and mortality or topics that may be derived from
3 stakeholder conversations.

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

13 So let's go to the next slide.

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

22 But we also had public input that informed

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

10 Let's go the next slide.

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

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

1 full range of interventions.

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

10 Let's go to the next slide.

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

1 relevance to a number of important issues.

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

6 Let's go to the next slide.

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

17 So let's go to the next slide.

18 So what we heard from you in October is
19 that the language in the research agenda should
20 continue to be action and solution oriented, and
21 that terminology and word choice should be precise,
22 consistent, and explicit rather than overly

1 conceptual to really make sure that everyone and our
2 stakeholders understood what we were articulating.

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

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

21 We also talked about in October, possibly
22 combining some complimentary statements such as the

1 elimination of health disparities and achieving of
2 health equity and statements that were related to
3 both of those. There was also a suggestion around
4 perhaps thinking about combining things like the
5 approaches for communicating evidence and
6 implementation science.

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

10 So let's go to the next slide.

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

20 We also, working with the Strategic
21 Planning Committee, combined statements that have
22 complimentary or related concepts. And that's one

1 of the reasons why we moved from 10 statements to
2 six statements. And the committee also simplified
3 the content by trying to focus on the statements and
4 revising the language to be more explicit and
5 consolidating some of the illustrative examples.

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

9 Let's go to the next slide.

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

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

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

1 stakeholder prioritized evidence gaps and the use of
2 data representative of diverse patient populations
3 and settings. So it brings both of those statements
4 together into the one that you see on the slide
5 here.

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

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

1 optimizing the full range of data resources.

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

12 The fifth statement around fund research
13 that focuses on health promotion and illness. I'm
14 sorry, health promotion and illness prevention by
15 addressing health drivers that occur where people
16 live, work, learn and play was one that had a lot of
17 discussion with the Strategic Planning Committee.
18 This was a simplified statement and focuses on the
19 research on health promotion and illness prevention
20 by addressing health drivers that occur where people
21 live, work and play. And it connects addressing
22 health drivers outside of the clinical setting as

1 being a key area for health promotion and illness
2 prevention.

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

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

16 Okay, let's go to the next slide.

17 So, as I talked about before, some of the
18 illustrative examples have also been updated as a
19 result of the combination of statements. And what
20 we're trying to do with these illustrative examples
21 is give some explanatory context to each of the
22 statements based on the feedback from the Board.

1 But also keep them separate from the official
2 research agenda. And so, you'll even see we use
3 some call-out boxes to try to really distinguish
4 that these illustrative examples are just examples
5 of how the research agenda statement may play out.

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

9 So for the first research agenda statement
10 here around funding research that fills patient
11 stakeholder prioritized evidence gaps and is
12 representative of diverse patient populations and
13 settings. You see three illustrative examples. One
14 that focuses on research on topics and outcomes of
15 relevance and value to patients and stakeholder
16 communities. Another that focuses on research that
17 recruit study participants that are representative
18 of communities most affected by conditions. And the
19 third one that's about research that involves
20 investigators that reflect the population or
21 community where the research is conducted and for
22 whom the research is intended.

1 So those three examples are thought to
2 provide some context into how that agenda statement
3 may translate into research items for PCORI.

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

16 We can go to the next slide.

17 So here you see our next two research
18 agenda statements, fund research that builds the
19 evidence base for emerging interventions by
20 leveraging the full range of data resources and
21 partnerships. And you see three illustrative
22 examples here. One that talks about leveraging

1 evidence synthesis and stakeholder engagement.
2 Another that focuses on innovations that are
3 identified through relationships with federal
4 partners. And a third that talks about using
5 optimized methods of data capture that are inclusive
6 of diverse sources of information.

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

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

18 So here you see our last two statements.
19 One on funding research that focuses on health
20 promotion and illness prevention. And the three
21 examples here, focus in on cross sector
22 collaboration with organizations that have expertise

1 in social determinants of health. The second
2 illustrative example focuses on research on upstream
3 topics, such as social determinants of health. And
4 the third one focuses on research that examines the
5 use of an investment in health promoting resources
6 in the community.

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

15 So the first illustrative example focuses
16 on research that studies the effectiveness of ways
17 to get information to the right people at the right
18 time, in the right way. The second example focuses
19 on approaches for rapid dissemination of evidence.
20 The third one is an example that focuses on research
21 on the effectiveness of implementation strategies.
22 And the fourth one is focused on research that

1 assesses methods for explaining things like
2 uncertainty, applicability, communicating risk.

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

9 Let's go to the next slide.

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

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

19 Then the public comment period would likely
20 go through late January and then following the
21 public comment period, the research agenda would be
22 revised accordingly.

1 And then the Board would be expected to
2 review the revised research agenda and consider it
3 for adoption at its March meeting.

4 So we can go to the next slide.

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

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

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

18 [Inaudible responses.]

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

21 It's very hard not to see people's faces so
22 -- okay. Thank you. Thank you.

1 All right. Well seeing some thumbs up
2 there then I'm going ask Rachel, if there's an
3 update to the attendance.

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

6 CHAIRPERSON GOERTZ: Thank you so much.

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

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

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

14 CHAIRPERSON GOERTZ: Thank you, Danny.

15 DR. LEVINE: This is Sharon, second.

16 CHAIRPERSON GOERTZ: Thank you very much,
17 Sharon.

18 All right. Is there any further
19 discussion?

20 [No response.]

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

1 [Ayes.]

2 CHAIRPERSON GOERTZ: Opposed?

3 [No response.]

4 CHAIRPERSON GOERTZ: Abstentions?

5 [No response.]

6 CHAIRPERSON GOERTZ: All right, thank you.

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

12 [Recess.]

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

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

19 DR. COOK: Excellent. And thank you.

20 So I'll just begin with, as you may recall,
21 we discussed approaches to monitoring our progress
22 against what's laid out in the Commitment Plan every

1 time we look at slates of awards, so I want to give
2 you this context for the slates under consideration
3 for approval this cycle, as well as provide you with
4 some context of how these slates compare to some of
5 the historical approaches within our PFAs.

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

12 Okay, let's go through the next slide.

13 So today the Board is going to consider the
14 following three slates for approval. Two of them
15 are research solicitations and one from an
16 infrastructure solicitation, and they total together
17 about \$67.5 million. And overall we're within the
18 Commitment Plan accounting for some of the shifts of
19 funds that we talked about in our Commitment Plan
20 discussion, where we had related to infrastructure,
21 some funds that shifted from fiscal year 2021 to
22 fiscal year 2022.

1 Our Cycle 1 overall had, I would say, more
2 limited offerings. We had fewer PFAs in cycle, one
3 of 2021. As you may recall, at that time, we were
4 working through several expedited COVID-related
5 funding announcements, and those hit the Commitment
6 Plan and fiscal year 2021. So they won't really
7 show up in our Commitment Plan for 2022 like the
8 other slates that you're looking at today.

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

15 So this slide just kind of demonstrates how
16 the funding cycles for the pragmatic clinical
17 studies or the PCS award slate fits into the larger
18 context of data related to letters of intent, the
19 applications and funding rates compared to our
20 historical average. And what you can see here is
21 that we had a pretty robust response to these
22 announcements with 36 letters of intent submitted.

1 And while this is lower than our historical average
2 this could relate to the fact that the timing of
3 issuance was essentially when we began issuing PCS
4 every cycle and are likely to see more of a
5 distribution of letters of intent across multiple
6 cycles. And that'll be different than our
7 historical, where we tended to have only two
8 offerings of pragmatic clinical studies each year.

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

15 We did invite over half of those that
16 submitted letters of intent to this solicitation to
17 submit applications and received almost 85 percent
18 of those that were invited. And we're proposing
19 today three for funding, and we'll continue to watch
20 these trends for Cycle 2 of 2021 as you see on the
21 right side of this slide, as we ramp up offerings
22 for different PCORI funding announcements, and we

1 may have to adjust as need be, given we are
2 increasing the offerings in the future cycles.

3 Okay. Can we go to the next slide?

4 This slide demonstrates how the Cycle 1
5 2021 broad PCORI funding announcement slate fits
6 into the larger context and how they compare to the
7 previous cycle. And what you can see here is that
8 this table is really intended to provide some
9 insight into whether a given cycle is typical or a
10 departure, and the slate is smaller than previous,
11 and may have been a bit unusual because we didn't
12 offer the broad PFA in Cycle 2 of 2020.

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

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

20 Cycle 3 of 2020 was the first full cycle
21 following the pandemic disruption and the higher
22 numbers that are there are likely to be a result of

1 that. And so, as we continue to look forward, the
2 next broad PFA slate that'll be considered will be
3 our Cycle 2 of 2021 that you see on the right of the
4 slide and then Cycle 3 of 2021. And thus far
5 they're looking similar percentage-wise to what
6 we've seen in the past. And historically, we have
7 seen a dip in applications in Cycle 2, and we're
8 trying to understand that trend as well.

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

16 But for now it's the first time that we're
17 issuing the full complement of PFAs as we talked
18 about in the Commitment Planning discussion and all
19 of the cycles. And we may also be seeing some
20 shifts related to that. And so, it's one of these
21 things that we're monitoring over the next several
22 cycles and hope to be able to tell you a little bit

1 more about what's happening there as we learn and do
2 some analysis of our aggregate numbers.

3 Let's go to the next slide.

4 So this slide demonstrates how the Phase 3
5 Coordinating Center for functions for PCORnet award
6 slate fit into the larger context and how it
7 compares to historicals. And what you can see here
8 is that Phase 1 was that design phase for the
9 network and was funded in 2014 at a level of about
10 \$14 million.

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

18 And then Phase 3, which is what we're
19 putting before you today is this period of
20 optimization. And the PFA here was a limited
21 competition PFA where PCORI solicited applications
22 from prime organizations that are currently funded

1 to participate in the Coordinating Center. And nine
2 applications were submitted and five are being
3 proposed here for funding for a total of \$18
4 million.

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

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

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

1 to the Commitment Plan at this time, but we do
2 anticipate that Cycle 2 and particularly Cycle 3,
3 hopefully, will have larger slates for us given we
4 have targeted PFAs that will appear in Cycle 2 and
5 Cycle 3.

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

9 CHAIRPERSON GOERTZ: Thank you, Nakela.

10 Are there any questions or comments from
11 the Board regarding our proposed commitments for
12 this particular slate?.

13 [No response.]

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

17 DR. DeVOE: Great. Thanks. I'm really
18 honored to be here on behalf of the Selection
19 Committee and our chair, Dr. Barbara McNeil and the
20 rest of the committee. We are here to recommend the
21 three award slates that Dr. Cook just highlighted
22 and set into context for us. Thank you, Nakela.

1 So this is a long process, as you know, so
2 in October and November, after many months of merit
3 review and staff review, our Selection Committee met
4 to consider these slates for the Cycle 1 2021
5 brought in pragmatic clinical study PFAs and the
6 Coordinating Center functions to advance Phase 3 of
7 PCORnet. And as usual, our committee engaged in
8 many robust discussions, reviewing the merit scores,
9 considering the program staff recommendations,
10 working with program staff to resolve issues that
11 were raised in review, assessing programmatic fit,
12 portfolio balance, and consistency with funding
13 announcements.

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

19 DR. KHAN: Great. Thanks so much, Jen. Hi
20 everyone. My name is Carly Khan. I'm an Associate
21 Director with the Healthcare Delivery and
22 Disparities Research Program, and I'm pleased to

1 present the Cycle 1 2021 pragmatic clinical studies
2 overview and slate recommendations for your
3 consideration today.

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

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

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

22 Next slide, please. I'll turn it back over

1 for discussion and vote.

2 CHAIRPERSON GOERTZ: Thank you so much
3 Carly.

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

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

12 [No response.]

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

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

19 CHAIRPERSON GOERTZ: Thank you.

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

1 trials PFA.

2 DR. FERNANDEZ: So moved.

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

5 DR. ZWOLAK: Second.

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

8 [No response.]

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

12 [Ayes.]

13 CHAIRPERSON GOERTZ: Opposed?

14 [No response.]

15 CHAIRPERSON GOERTZ: Abstentions?

16 [No response.]

17 CHAIRPERSON GOERTZ: All right. Thank you.

18 Now we're going to move on to our next
19 slate. This discussion is going to be led by Steve
20 Clauser and Holly Ramsawh.

21 Steve and Holly, are you ready to go?

22 DR. CLAUSER: Yes, we are.

1 CHAIRPERSON GOERTZ: All right.

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

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

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

18 The second study just below that on the
19 slate addresses our congressionally mandated special
20 area of emphasis related to maternal mortality and
21 morbidity and compare strategies to improve outcomes
22 and reduce disparities in pregnant women with

1 general herpes simplex virus infection.

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

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

12 Next slide. Now, I'll turn it over to
13 Holly Ramsawh.

14 DR. RAMSAWH: Okay, thanks.

15 Thank you. I'm happy to present the slates
16 for both the assessment of prevention, diagnosis,
17 and treatment options and improving methods for
18 conducting PCOR. For the first slate, this is a
19 pragmatic randomized controlled trial that seeks to
20 compare the effectiveness of a non-steroidal anti-
21 inflammatory drug versus a low dose opioid analgesic
22 regimen on pain management.

1 And for the second slate, the overarching
2 objective of the project is to develop new
3 statistical methods for instrumental variable
4 designs that incorporate modern machine learning
5 approaches.

6 Next slide please.

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

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

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

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

20 [No response.]

21 CHAIRPERSON GOERTZ: All right. Hearing no
22 requests for discussion, then I'd like to ask for a

1 motion to approve funding for the recommended slates
2 of awards from the Cycle 1 2021 Broad PFAs.

3 DR. HERNDON: Mike, so moved.

4 CHAIRPERSON GOERTZ: Thank you, Mike.

5 DR. LEVINE: Sharon, second.

6 CHAIRPERSON GOERTZ: Thank you, Sharon.

7 Actually, Sharon, I think you're recused.

8 DR. LEVINE: I take it back.

9 [Laughter.]

10 DR. ZWOLAK: It's Bob, second.

11 CHAIRPERSON GOERTZ: Okay. I heard Bob.

12 So let's go with Bob. Thank you.

13 All right. Is there any further
14 discussion?

15 [No response.]

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

19 [Ayes.]

20 CHAIRPERSON GOERTZ: Opposed?

21 [No response.]

22 CHAIRPERSON GOERTZ: Abstentions?

1 [No response.]

2 CHAIRPERSON GOERTZ: Okay, thank you.

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

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

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

18 So if we could go to the next slide.

19 Before we talk about the specifics of the
20 PFA, I just wanted to remind folks briefly about the
21 work that the PCORnet Priorities Working Group of
22 this Board did last winter to develop a set of

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1 prioritizing principles for PCORnet and its future
2 funded activities, to provide guidance to PCORI
3 staff on the parameters for Phase 3 of PCORnet, as
4 well as guidance that can inform our ongoing program
5 oversight once the awards go into effect.

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

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

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

22 Just also a brief note before we move on to

1 the PFA that the working group will be continuing
2 its work in coordination with the ongoing Strategic
3 Planning process that PCORI is in the process of,
4 and so, they will be working and you'll be hearing
5 more from them in 2022.

6 Next slide please.

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

18 The specifics for the different functional
19 scopes are of course, beginning with the Program
20 Management Office to facilitate the logistics and
21 coordination across all of the network activities.
22 Also with a particular focus on ensuring that there

1 is coordination and integration of all of the
2 Coordinating Center functions across any awardees.

3 Second then, is the maintenance and
4 development of the common data model.

5 Moving then to scope three, where we will
6 have the functions related to the query functions
7 and analytic tool development to enable multi-site
8 network research to be accomplished through the
9 PCORnet.

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

17 And finally then, is the fifth functional
18 element is a new function for the Coordinating
19 Center. And that is one that is dedicated to
20 engagement of all the PCORnet stakeholders. Really
21 working to also capture the learnings and best
22 practices from across the network sites and

1 promoting awareness of them, disseminating them to
2 other networks, as well as to others to make sure
3 that those best practices are learned and able to be
4 capitalized upon across all of the network
5 activities.

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

13 DR. LEVINE: Thanks so much, Laura.

14 And before we open this for discussion, the
15 following Board members have notified us of their
16 intention to recuse themselves from the discussion
17 and from the vote on the infrastructure slate award
18 slate. I've already mentioned Christine Goertz,
19 Jennifer DeVoe, Mike Lauer, James Schuster, and both
20 Michelle McMurry-Heath, and Barbara McNeil, who had
21 previously indicated their intention to recuse
22 themselves but are unable to attend a meeting.

1 So can I get a motion to approve funding
2 for the recommended slate of awards from the Cycle 2
3 2021 Coordinating Center functions to advance Phase
4 3 of PCORnet. And then, with the motion and a
5 second, we'll open it for discussion.

6 DR. HOWERTON: Russ Howerton, motion.

7 DR. ZWOLAK: Bob, second.

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

10 [No response.]

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

14 [Ayes.]

15 DR. LEVINE: Opposed?

16 [No response.]

17 DR. LEVINE: Any abstentions?

18 [No response.]

19 DR. LEVINE: The motion passes. Great.

20 Okay. I will turn this back to Nakela to
21 provide an overview of the targeted PFA development
22 to be considered for approval today.

1 DR. COOK: Excellent. Well, thank you so
2 much, Sharon. And I'm looking forward to talk to a
3 little bit about the targeted PFAs that are being
4 put before the Board for consideration in the
5 context of that expedited and enhanced process we
6 spoke about for the development of PFAs.

7 So let's go to next slide.

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

21 And we're really excited to see how they
22 pan out so that we can have some insights as we move

1 forward with this next approach for the following
2 year.

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

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

22 We also know that we're starting to see

1 some of the letters of intent and applications
2 coming in, where we may have robust responses and
3 where we may have to tweak or resubmit and -- I
4 should say, tweak or allow for resubmissions in
5 order to reach some of the goals of PFA.

6 So that's another component of this
7 approach.

8 Let's go to the next slide.

9 So back in April, the Board approved that
10 large set of candidate topics for targeted PFAs or
11 special areas of emphasis development through the
12 2022 funding cycles. So you can see on the left,
13 the topics that have moved forward as targeted PCORI
14 funding announcements. And today we're going to
15 discuss substance abuse in youth -- and substance
16 abuse in youth, as well as delirium for release in
17 Cycle 2 of 2022. And the remaining topics that you
18 see on the right of the slide are still under
19 development.

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

1 disabilities related topics.

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

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

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

1 approach with a targeted solicitation that follows.

2 Let's go to the next slide.

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

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

20 So both of these are presented today as
21 part of that set of the candidate topics for
22 targeted PFA development. And they really do

1 represent a wider range of study duration and
2 funding level to allow for different study designs
3 and sizes. And we're also offering more than one
4 cycle as warranted to allow for deferrals and
5 resubmission.

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

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

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

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

21 DR. HOUTSMULLER: Yes. Thank you, Alicia.

22 Next slide please.

1 So this -- the research question for this
2 proposed targeted PFA focuses on the comparative
3 effectiveness of brief behavioral interventions that
4 are adapted for adolescents ages 12 to 17 to address
5 alcohol use.

6 Next slide please.

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

14 And then there are several other outcomes
15 of interest also listed on this slide.

16 We would require a 12-month follow-up. And
17 the total amount that we are requesting is \$30
18 million. We're estimating that we would release
19 this PFA up to three cycles, and we're expecting to
20 fund three-to-five studies with a maximum project
21 duration of up to five years.

22 Next slide please.

1 I will now hand it back to Alicia for all
2 discussion and a okay.

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

7 DR. AYERS: So moved, Kara.

8 DR. FERNANDEZ: Thank you, Kara.

9 Do we have a second?

10 DR. HERDON: Mike, second.

11 DR. FERNANDEZ: Thank you, Mike.

12 Is there discussion?

13 [No response.]

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

17 All in favor.

18 [Ayes.]

19 DR. FERNANDEZ: All opposed?

20 [No response.]

21 DR. FERNANDEZ: Any abstentions?

22 [No response.]

1 DR. FERNANDEZ: So I look forward and hope
2 the research community reacts to this great TPFA.
3 Thank you all.

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

8 Please go ahead, Dr. Akinbami.

9 DR. AKINBAMI: Thank you, Alicia.
10 Next slide please.

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

16 Next slide please.

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

1 populations in the PFA.

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

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

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

22 Overall, we are requesting a total

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1 commitment of \$30 million, depending on the
2 applications received. These targeted funding
3 announcement could be released for up to three
4 cycles in order to fund up to three to five studies.
5 with the maximum duration of up to five years.

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

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

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

19 Can you kind of talk to me about what our
20 aim is more specifically than kind of delirium,
21 because to me, delirium is kind of broad in
22 description.

1 DR. AKINBAMI: Thank you for that question.

2 So we do realize that delirium is broad,
3 but so we're interested and we do realize that
4 delirium is multifactorial in our region. And so,
5 that's why we have focused this topic on older
6 adults, 65 years and older. And we will be
7 interested in patients who have been diagnosed with
8 either delirium or at-risk of delirium in medical
9 settings and long-term care settings.

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

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

19 DR. HERNDON: Yeah. I think in my
20 experience, the most common cause of delirium in the
21 adult population is medication induced, you know,
22 medication reactions. So anyway, yeah, I just kind

1 of was wanting to focus and just get a little bit
2 better understanding.

3 Alicia, do you --

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

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

22 And so, we are looking for studies and

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

6 DR. HERNDON: Understood. I get it now.
7 Thank you.

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

11 Are there any other comments or questions
12 at this point?

13 [No response.]

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

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

19 CHAIRPERSON GOERTZ: Great. Thank you so
20 much.

21 All right. Do I have a motion to approve
22 the development of the prevention, early

1 identification, and treatment of delirium targeted
2 PFA with funding up to \$30 million in total costs?

3 [Multiple speakers.]

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

6 DR. HERNDON: Mike, so moved.

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

9 DR. RHODES: Karin, second.

10 CHAIRPERSON GOERTZ: Sorry who was that
11 second?

12 DR. RHODES: Karin Rhodes, second.

13 CHAIRPERSON GOERTZ: Oh, thank you, Karin.
14 All right. Is there any further
15 discussion?

16 [No response.]

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

19 [Ayes.]

20 CHAIRPERSON GOERTZ: Opposed?

21 [No response.]

22 CHAIRPERSON GOERTZ: Abstentions.

1 [No response.]

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

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

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

16 And those of us who worked in those
17 provider-affiliated networks, hospital, and provider
18 networks, which was, you know, I had 15 years of
19 practice in one. It makes a lot of sense for boots
20 on the ground providers to be involved in these
21 implementation strategies. So I'm very excited
22 about this. These projects will take place directly

1 within the health care delivery systems in other
2 words.

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

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

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1 quotes with provider and patient engagement.

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

6 DR. SIEGEL: Great. Thank you, Mike.

7 Next slide please.

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

15 Traditionally, research funders have
16 focused on publication as the end goal of research.
17 Publication is of course a critical step, but at
18 PCORI, we have an explicit commitment to steps
19 beyond publication, including the prompt release of
20 findings. And that is accessible plain language
21 findings to the public. The active dissemination of
22 findings to increase knowledge and awareness among

1 our target audiences who can use them.

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

7 Next slide, please.

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

17 HSII will complement our current funding
18 initiatives in D&I. These initiatives, three of
19 them, include both limited and open competition
20 opportunities and they focus on different evidence,
21 but what they all share is that they're led by
22 investigator teams. Most often researchers who have

1 a previous PCORI-funded research award or who've
2 done related research. HSII will be different in
3 that it will allow us to work directly with
4 provider-affiliated health plans that have an
5 important role in healthcare delivery and with
6 healthcare delivery systems.

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

17 And in addition, we expect that
18 implementation activities through HSII will lay
19 groundwork for future scale-up in other health
20 systems by adapting and demonstrating pathways to
21 uptake and towards documenting the impact of those
22 efforts.

1 We also expect HSII to be a learning
2 opportunity and to facilitate the transfer of
3 learnings across healthcare systems. Next slide.

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

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

22 So today, what we'd like to do is describe

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1 the HSII award program and to request Board approval
2 for those two elements, the approval framework for
3 HSII implementation projects and a funding
4 commitment for HSII. Next slide.

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

15 Immediately after their acceptance as HSII
16 participants, these organizations will have the
17 opportunity to apply for PCORI funding to undertake
18 capacity building projects. The goal of this
19 capacity building opportunity is to strengthen HSII
20 participants' ability to undertake implementation
21 efforts essentially to help these participants build
22 toward a successful experience.

1 These kinds of funds could go, for example,
2 redesigning staff roles, developing advisory
3 committees or building internal teams or enhancing
4 data systems or tools.

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

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

16 Next slide.

17 HSII is intended to accomplish these goals
18 on the road toward building to PCORI's goal of
19 moving evidence from research into real-world
20 practice. These goals will be how we measure
21 success and what our program evaluation will need to
22 assess. We want to demonstrate feasible and

1 scalable approaches for integrating evidence into
2 practice. That is we want the HSII participants to
3 adapt and then use approaches that work for them in
4 getting evidence into practice in their systems.

5 They must be scalable approaches that have
6 the potential to work beyond any specific
7 implementation project environment. We want HSII to
8 accomplish meaningful uptake in diverse healthcare
9 delivery settings through the implementation
10 projects. In order to show that an approach to
11 implementation works, it has to actually accomplish
12 the change in practice.

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

21 Specifically, AHRQ has national reach, a
22 mandate to conduct D&I of PCOR, an interest in

1 accomplishing broad scale implementation, building
2 on successful implementation of evidence outside the
3 research context.

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

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

20 Next slide.

21 Implementation projects will all conduct
22 program evaluation in HSII, and it will examine

1 implementation process outcomes that document the
2 completion of implementation activities, and also
3 impacts on healthcare and health outcomes. These
4 are the types of outcomes we assess in all the PCORI
5 D&I projects. However, with HSII we'll have the
6 additional opportunity to conduct the longer-term
7 evaluation.

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

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

18 One final component of HSII that I'd like
19 to note, is that we'll put in place a learning
20 network for participants to support and facilitate
21 their success in this initiative. The learning
22 network will serve several purposes. It'll provide

1 a venue for participants to share experiences in
2 planning and executing implementation efforts, and
3 also in addressing challenges that will inevitably
4 arise. It will provide resources and learning
5 opportunities to support the participants. And
6 importantly, it will provide an opportunity for HSII
7 participants to weigh-in on the PCORI's proposed
8 topics for implementation or suggest topics based on
9 PCORI-funded research.

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

15 Next slide please.

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

19 First, these are the principles we use to
20 guide the development of the review and approval
21 process or framework for HSII. The Board of
22 Governors and the EDIC have underlined the

1 importance of speed and efficiency in getting
2 findings from research into practice. We also heard
3 a lot about this from our RFI respondents. So this
4 is a primary goal.

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

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

18 Next slide, please.

19 In the next couple of slides, I'm going to
20 describe the approval framework for each of the
21 three HSII steps. Starting with this step one, the
22 selection of HSII participants to join the

1 initiative. Applicant organizations, these are the
2 healthcare delivery systems and provider-affiliated
3 health plans, will submit applications in response
4 to an initial call for proposals to become HSII
5 participants. Merit review and PCORI staff will be
6 responsible for the review of these applications.
7 The Executive Director or Designee will then
8 consider and make decisions regarding the approval
9 of applicants to join HSII.

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

13 Next slide, please.

14 Step two is again, the step where HSII
15 participants have the opportunity to apply for
16 initial fundings to strengthen their ability to
17 conduct successful implementation projects under
18 HSII. So immediately after they're selected as HSII
19 participants, they'll be able to propose projects in
20 response to a call for HSII capacity building
21 project proposals. Their proposed projects may have
22 budgets up to \$500,000.

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1 PCORI staff and external experts will
2 review the proposals and the Executive Director or
3 Designee will make the funding decisions for slates
4 of these awards. This approval process for the
5 capacity building projects is quite similar to Board
6 approved processes for the approval of small D&I
7 awards that have similar budgets. And also for the
8 engagement awards, both of which are approved by the
9 Executive Director or Designee.

10 Next slide.

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

16 To begin with HSII participant input, PCORI
17 will identify the evidence focus for the
18 implementation projects and issue topic-specific
19 calls for implementation project proposals. HSII
20 participants can respond to as many of these calls
21 for proposals as they wish with the implementation
22 projects being proposed having a budget of \$1 to \$5

1 million in a range from two to five years in length.

2 Next slide.

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

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

22 The EDIC which serves as the selection

1 committee for the D&I awards program will then
2 consider projects recommended by PCORI staff and
3 recommend slates of awards to the Executive
4 Director. The EDIC has significant experience in
5 this role having served as the selection committee
6 for the large D&I funding awards for the past
7 several years for all three of the D&I programs
8 funding initiatives.

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

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

19 So this is the approval framework we're
20 asking you to approve today, along with the
21 commitment of funding for the HSII award program at
22 the level of \$15 million per fiscal year, beginning

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1 this year, not to exceed a total of over \$50 million
2 over five years.

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

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

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

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

20 DR. SIEGEL: Sure. We thought a lot about
21 that because we're expecting to have systems that
22 obviously have different size and different current

1 capacity. And we asked this question explicitly in
2 the RFI in order to get kind of more feedback. We
3 did get, I think, 24 responses to the RFI. So we
4 got a good deal of input. And almost unanimously,
5 there was positive response to that.

6 What people told us was that you know, it
7 was likely that projects would be stepwise in any
8 case. And this initial support would be very
9 helpful in kind of plugging up some holes. It might
10 not build a full capacity for all systems.
11 Clearly, it's not at that level. But it would be a
12 good start and a good opportunity for people to
13 basically build strength where they need it.

14 So that's what we're hoping it'll be used
15 for.

16 DR. SCHUSTER: Okay. Thanks.

17 DR. HERNDON: And James, I might just add
18 to that, you know, I think -- what you know, I
19 envisioned was, you know, most of these systems are
20 going to have their Chief Quality Officers.
21 And the Chief Quality Officer may be the one who
22 kind of oversees, you know, these efforts, you know.

1 But they're going to need support staff. Maybe the
2 practice facilitator, you know, the person who goes
3 out into the actual clinics to help.

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

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

14 CHAIRPERSON GOERTZ: Any additional
15 comments or questions?

16 [No response.]

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

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

22 CHAIRPERSON GOERTZ: Thank you so much.

1 All right, I'm going to ask for a motion to
2 approve the proposed framework for the HSII
3 implementation projects, including PCORI staff
4 reviews of proposals, the EDIC consideration of
5 projects, and recommendation of slate of awards, and
6 Executive Director consideration and approval of
7 slate of awards.

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

14 DR. LEVINE: So moved. Sharon Levine.

15 CHAIRPERSON GOERTZ: Thank you, Sharon.

16 DR. FERNANDEZ: Second.

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

19 [No response.]

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

1 [Ayes.]

2 CHAIRPERSON GOERTZ: Opposed?

3 [No response.]

4 CHAIRPERSON GOERTZ: Abstentions?

5 [No response.]

6 CHAIRPERSON GOERTZ: All right. Thank you.

7 DR. SIEGEL: Thanks very much.

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

13 Can Nakela or Michelle or Kristin, please
14 confirm that?

15 DR. CARMAN: That's correct. No one has
16 registered for public comment.

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

21 DR. COOK: Thanks Christine. And what an
22 exciting meeting, a rich meeting with lots of great

1 discussion, and I just wanted to appreciate the
2 Board members for all the input on the many rich
3 agenda items today and the feedback on things such
4 as the Dashboard. And I heard a lot of great
5 comments, including the importance of the work of
6 the Strategic Planning committee and taking on some
7 activity related to thinking about the evaluation
8 and evaluation metrics that will serve us well as we
9 move into our next phase under our new Strategic
10 Plan.

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

18 I'm also really excited, as I think a lot
19 of the staff at PCORI will be, to move forward
20 toward the new targeted PFAs that were approved by
21 the Board today, as well as the health systems
22 implementation initiative. It's a really exciting

1 time for us. And I would be remiss if I didn't say
2 congratulations to all the awardees for the slates
3 that were approved today. And we will continue to
4 do our work to fulfill next year's Commitment Plan
5 targets and look forward to moving all these items
6 forward to do so.

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

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

17 CHAIRPERSON GOERTZ: Thank you so much,
18 Nakela. I really, really appreciate all of the work
19 -- thanks to you and the staff for all of the work
20 that went into a planning of this very rich meeting.
21 Thank you to Board members for hanging in with us
22 over two full days. We are -- just a reminder that

1 you're not quite done yet. We are going to be
2 engaging in a planning session that will start in --
3 why don't we start that at 3:30 Eastern time. So in
4 just a few minutes.

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

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

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

18 Thanks again for joining us and have a
19 terrific afternoon.

20 Take care.

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

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