February 28, 2022

William F. Marshall
Judicial Watch, Inc.
425 Third Street SW, Suite 800
Washington, DC 20024

Re: NIH FOIA Case No.: 56471; Judicial Watch v. HHS, Case No. 21-cv-02302

Dear Mr. Marshall:

This is a partial response to the Freedom of Information Act (FOIA) request that is the subject of the complaint filed in Judicial Watch v. HHS, 21-cv-02302, now pending in the U.S. District Court for the District of Columbia. Your FOIA request, dated June 8, 2021, was received by the National Institutes of Health (NIH) on the same day.

You requested all emails sent to and from Director Francis Collins related to “gain of function”, “hydroxychloroquine”, "HCQ", and/or "Wuhan Institute of Virology" for the date range of October 1, 2019 to June 8, 2021.

In accordance with the Court’s order dated August 31, 2021, NIH has processed 300 pages responsive to your request. NIH has sent 54 pages to outside stakeholders for consultation. NIH will provide a further response regarding this material once the consultations are complete. Attached to this letter are 199 pages from the current production.

NIH has determined that some of the pages retrieved by the search are non-responsive to your request. A total of 6 pages from the November production, 122 pages from the December production, 7 pages from the January production and 47 pages from the current February production are non-responsive and will not be produced.

I have determined to withhold portions of the enclosed pages under FOIA exemptions (b)(4), (b)(5) and (b)(6). The information being withheld is protected from release pursuant to Exemptions 4, 5, and 6 of the FOIA, 5 U.S.C. § 552 (b)(4), (b)(5) and (b)(6); and sections 5.31(d), (e) and (f) of the HHS FOIA Regulations, 45 CFR Part 5. Exemption 4 protects from disclosure trade secrets and commercial or financial information that is privileged and confidential. Exemption 5 permits the withholding of internal government records which are pre-decisional and contain staff advice, opinion, and recommendations. This exemption is intended to preserve free and candid internal dialogue leading to decision-making. Exemption 6 exempts from disclosure records the release of which would cause a clearly unwarranted invasion of personal privacy.
Please direct any questions regarding this response to Derek Hammond of the Department of Justice, who can be reached at Derek.Hammond@usdoj.gov.

Sincerely,

Gorka Garcia-Malene
Freedom of Information Act Officer, NIH
# Cycle 3 2019 – Broad PFAs

## Merit Review Criteria

<table>
<thead>
<tr>
<th>Broad PFAs (excluding Methods)</th>
<th>Improving Methods for Conducting Patient-Centered Outcomes Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Potential for the study to fill critical gaps in evidence</td>
<td>1. <strong>Study identifies critical methodological gap(s)</strong> in PCOR/CER</td>
</tr>
<tr>
<td>2. Potential for the study findings to be adopted into clinical practice and improve delivery of care</td>
<td>2. <strong>Potential for the study to improve PCOR/CER methods</strong></td>
</tr>
<tr>
<td>3. Scientific merit (research design, analysis, and outcomes)</td>
<td>3. Scientific merit (research design, analysis, and outcomes)</td>
</tr>
<tr>
<td>4. Investigator(s) and Environment</td>
<td>4. Investigator(s) and Environment</td>
</tr>
<tr>
<td>5. Patient-centeredness</td>
<td>5. Patient-centeredness</td>
</tr>
<tr>
<td>6. Patient and stakeholder engagement</td>
<td>6. Patient and stakeholder engagement</td>
</tr>
</tbody>
</table>
Cycle 3 2019 – Broad PFAs
Process Overview

- 176 Letters of Intent (LOIs) received
- 91 LOIs invited to submit a full application
- 70 applications were received
- The Selection Committee is proposing to fund 10 applications* out of 70 received applications for a funding rate of 14%.

*Recommended by the Selection Committee on June 12, 2020
Cycle 3 2019 – Addressing Disparities
Slate of 3 Recommended Projects

<table>
<thead>
<tr>
<th>Project Title</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Comparative Effectiveness of Individual Versus Group-level Interventions to Reduce HIV Risk among African Immigrant Women</strong></td>
</tr>
<tr>
<td>Diabetes Medical Nutrition Therapy in Southeastern African American Women</td>
</tr>
<tr>
<td><strong>Online Cognitive Behavioral Therapy for Depressive Symptoms in Rural Patients with Coronary Heart Disease</strong></td>
</tr>
</tbody>
</table>

Resubmissions in bold
Cycle 3 2019 – Assessment of Prevention, Diagnosis, and Treatment Options
Slate of 1 Recommended Project

Project Title

Addressing Anxiety among Low-Risk Chest Pain Patients in the Emergency Department Setting

Resubmissions in bold

NIH - 000904
## Project Title

<table>
<thead>
<tr>
<th>Project Title</th>
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<tbody>
<tr>
<td>Elders Preserving Independence in the Community (EPIC)</td>
</tr>
<tr>
<td>Comparing the Effectiveness of Two Approaches to Preventing Severe Hypoglycemia</td>
</tr>
<tr>
<td>Comparing Fingerstick Blood Glucose Monitoring versus Continuous Glucose Monitoring in Primary Care</td>
</tr>
<tr>
<td>Comparative Effectiveness Trial of Perioperative Telemonitoring for Functional Recovery and Symptoms</td>
</tr>
</tbody>
</table>

Resubmissions in bold
<table>
<thead>
<tr>
<th>Project Title</th>
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</thead>
<tbody>
<tr>
<td>Missing Data When Transporting Treatment Effects from Clinical Trials to a Target Population</td>
</tr>
<tr>
<td>An Efficient Distributed Learning Framework for Integrating Evidence in Clinical Research Networks</td>
</tr>
</tbody>
</table>

Resubmissions in bold

NIH - 000906
### Cycle 3 2019 Recommended Slate of 10 Projects

<table>
<thead>
<tr>
<th>PFA</th>
<th>Amount Budgeted</th>
<th>Proposed Total Award*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cycle 3 2019 Broad</strong></td>
<td>$15M</td>
<td>$24.9M</td>
</tr>
</tbody>
</table>

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.*
Call for a Motion to:
- Approve funding for the recommended slate of awards from the Cycle 3 2019 Broad PFAs

Call for the Motion to be Seconded:
- Second the Motion
  - If further discussion, may propose an Amendment to the Motion or an Alternative Motion

Roll Call Vote:
- Vote to Approve the Final Motion
  - Ask for votes in favor, opposed, and abstentions
Limited Competition: Dissemination and Implementation PFA

Implementation of PCORI-Funded Patient-Centered Outcomes Research Results

Cycle 3 2019 Award Slate

Lawrence Becker
Chair, Engagement, Dissemination, and Implementation Committee

Joanna Siegel, SM, ScD
Director, Dissemination and Implementation Program

NIH - 000909
## Limited Competition PFA

<table>
<thead>
<tr>
<th></th>
<th>Criteria</th>
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<tbody>
<tr>
<td>1</td>
<td>Importance of research results in the context of the existing body of evidence</td>
</tr>
<tr>
<td>2</td>
<td>Readiness of the research results for implementation</td>
</tr>
<tr>
<td>3</td>
<td>Technical merit of the proposed implementation project</td>
</tr>
<tr>
<td>4</td>
<td>Project personnel and environment</td>
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<tr>
<td>5</td>
<td>Patient-centeredness</td>
</tr>
<tr>
<td>6</td>
<td>Patient and stakeholder engagement</td>
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</tbody>
</table>
Cycle 3 2019 - Limited Competition Dissemination and Implementation PFA

Process Overview

- 11 Letters of Intent (LOIs) submitted
- 7 LOIs invited to submit a full application
- 6 applications received

Proposed funding slate is recommended by the Engagement, Dissemination, and Implementation Committee (EDIC)

- Proposing to fund 1 applications out of the 6 received
- Funding rate is 17 percent
<table>
<thead>
<tr>
<th>Project Title</th>
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</thead>
<tbody>
<tr>
<td>Implementing Best-Practice, Patient-Centered Venous Thromboembolism Prevention in Trauma Centers</td>
</tr>
</tbody>
</table>
**Cycle 3 2019 - Limited Competition Dissemination and Implementation PFA**

Slate of 1 Recommended Project

<table>
<thead>
<tr>
<th>PFA</th>
<th>Amount Budgeted [per Year]</th>
<th>Proposed Total Award*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation of PCORI-Funded Patient-Centered Outcomes Research Results</td>
<td>$9.0M</td>
<td>$1.4M</td>
</tr>
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</table>

Note: Budgeted amount is for up to 3 cycles per year; $6.1M awarded during first two cycles of 2019.

* All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract

NIH - 000913
Board Vote

Call for a Motion to:

- Approve funding for the recommended award slate from the Cycle 3 2019 Limited Competition Implementation of PCORI-Funded Patient-Centered Outcomes Research Results PFA

Call for the Motion to Be Seconded:

- Second the Motion
  - If further discussion, may propose an Amendment to the Motion or an Alternative Motion

Roll Call Vote:

- Vote to Approve the Final Motion
  - Ask for votes in favor, opposed, and abstentions
Wrap Up and Adjournment

202.827.7700
info@pcori.org
www.pcori.org

@pcori
/PCORInstitute
PCORI
/pcori
### AGENDA

<table>
<thead>
<tr>
<th>Time</th>
<th>Agenda Item</th>
<th>PCORI Speakers</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:00-</td>
<td>Call to Order, Roll Call, and Welcome</td>
<td>Christine Goertz, DC, PhD, Chairperson and Nakela Cook, MD, MPH, Executive Director</td>
</tr>
<tr>
<td>1:00-1:05</td>
<td>Consider for Approval: May 5, 2020 Board Minutes</td>
<td>Christine Goertz, DC, PhD</td>
</tr>
<tr>
<td>1:05-1:45</td>
<td>Executive Director’s Report</td>
<td>Nakela Cook, MD, MPH</td>
</tr>
<tr>
<td>1:45-2:10</td>
<td>Update on COVID-19 Initiatives</td>
<td>Nakela Cook, MD, MPH</td>
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<tr>
<td></td>
<td>Consider for Approval: Additional Funding for COVID-19 Enhancements and Targeted PFAs</td>
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<tr>
<td>2:10-2:35</td>
<td>Consider for Approval: Funding Announcement</td>
<td>Robert Zwolak, MD, PhD, Chair, Science Oversight Committee and Els Houtsmuller, PhD, Associate Director, Healthcare Delivery and Disparities Research (HDDR)</td>
</tr>
<tr>
<td>2:35-3:00</td>
<td>Consider for Approval: Award Slates</td>
<td>Barbara McNeil, MD, PhD, Chair, Selection Committee, Stanley Ip, MD, Interim Program Director, Clinical Effectiveness and Decision Science (CEDS) and Steven Clauer, PhD, MPA, Program Director, HDDR</td>
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NIH - 000916
<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>3:00</td>
<td>Wrap up and Adjournment</td>
<td>Christine Goertz, DC, PhD</td>
</tr>
</tbody>
</table>

*Implementation Committee (EDIC) and Joanna Siegel, SM, ScD, Director, Dissemination and Implementation Program*
Board of Governors Meeting via Teleconference / Webinar  
Tuesday, May 5, 2020  
11:00 am - 2:30 pm ET

MINUTES

Board Members Present:  
Christine Goertz, DC, PhD, Chairperson; Sharon Levine, MD, Vice Chairperson; Kara Ayers, PhD; Larry Becker; Michael Lauer, MD (designee for Francis Collins, MD, PhD); Jennifer DeVoe, MD, DPhil; Christopher Friese, PhD, RN; Russell Howerton, MD; Gail Hunt; Freda Lewis-Hall, MD; David Meyers, MD (designee for Gopal Khanna, MBA); Michelle McMurry-Heath, MD, PhD; Barbara McNeil, MD, PhD; Grayson Norquist, MD, MSPH; Kathleen Troeger, MPH; Janet Woodcock, MD; Robert Zwolak, MD, PhD

Board Members Absent:  
Alicia Fernandez, MD; Michael Herndon, DO; Ellen Sigal, PhD

Guest Speakers: Chris Forrest, MD, PhD, Children’s Hospital of Philadelphia and Susanna Naggie, MD, Duke Clinical Research Institute

Executive Team: Nakela Cook, MD, MPH, Executive Director; Josie Briggs, MD; Mary Hennessey, Esq.; Michele Orza, ScD, Tasha Parker, Jean Slutsky, PA, MSPH; Regina Yan, MA

<table>
<thead>
<tr>
<th>Agenda Item</th>
<th>Related Minutes</th>
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<tbody>
<tr>
<td>Call to Order, Roll Call, and Welcome</td>
<td>Dr. Goertz chaired and opened the meeting, welcomed all to the meeting of the PCORI Board of Governors and read the Chair Statement on Conflict of Interest. Dr. Goertz acknowledged the contributions of Dr. Josephine Briggs who served as the Acting Executive Director and is now serving as the Acting Chief Science Officer. She also welcomed the new Executive Director, Dr. Nakela Cook, who joined PCORI on April 15, 2020. She then reviewed the meeting agenda.</td>
</tr>
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</table>

Consider for Approval:  
- Minutes of the March 2 and April 1, 2020 Board Meetings  
- Proposed Amendments to PCORI Bylaws

- Christine Goertz, DC, PhD, Sharon Levine, MD, Chair, Governance Committee, and Mary Hennessey, General Counsel

The following motion was made by Sharon Levine and seconded by Freda Lewis-Hall.

Motion: Approve minutes from the March 2, 2020 and April 1, 2020 Board of Governors meetings.

Approved by a majority vote of the voting Board members by voice vote (no opposed; no abstentions); Jennifer DeVoe and Janet Woodcock were not present for this vote.
### Executive Director’s Report

- **Nakela Cook, MD, MPH**

Dr. Nakela Cook introduced herself as PCORI’s new Executive Director. She shared information on her educational and career background, and how it has shaped her path to PCORI. She acknowledged the effective efforts of staff in working together remotely during the COVID-19 pandemic and of the Board in shifting its work and meeting to a virtual format.

Cook provided background on what she envisions for PCORI 2.0, opportunities for PCORI’s future, and how PCORI can learn during a public health crisis. She brought attention to PCORI’s opportunities to leverage innovations in healthcare to promote the science of delivery for improved outcomes. She brought

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Dr. Goertz then asked Sharon Levine, Chair of the Governance Committee, to introduce the proposed amendments to PCORI’s Bylaws.

Dr. Levine noted that PCORI’s reauthorizing law includes new and revised provisions addressing governance that should be reflected in PCORI’s Bylaws to maintain consistency and accuracy. Mary Hennessey then summarized the proposed amendments which track language in the reauthorization law relating to:

- GAO’s appointment of Board members regarding the preserving of evenly staggered terms of Board members and the process for filling vacancies created by Board members who leave the Board before the end of their term;
- Shift in authority for the appointment of Methodology Committee members from the Comptroller General of the United States to the PCORI Board;
- Updating the legal citation referenced from the authorizing law to the reauthorizing legislation; and,
- Clarifying language confirming that Committees, working groups and ad hoc committees shall not exercise the power of the Board except as authorized by the Board.

_The following motion was made by Robert Zwolak and seconded by Gail Hunt._

**Motion: Approve the Amended Bylaws**

*Approved by a majority vote of the voting Board members by roll call (15 in favor; no opposed; no abstentions); Jennifer DeVoe and Janet Woodcock were not present for this vote.*
focus to the urgency of addressing health disparities in the United States. She then outlined the opportunities that PCORI has to accelerate its impact on care delivery and patient health outcomes.

Cook shared her vision for PCORI 2.0, as a cycle of evidence to implementation, integrating research and health care while leveraging data and technology. She stated that her first year focus will be on shared principles, onboarding, PCORI’s response to the COVID-19 pandemic, National Priority setting, topic generation process, and other priorities stemming from PCORI’s authorizing law. She outlined a collaborative strategy to advance this vision.

Cook provided an overview of PCORI’s approach in response to the COVID-19 health crisis. She shared PCORI’s three priority areas: health care delivery, vulnerable populations, and health care workers. She described PCORI’s approach including funding new awards, enhancing of existing awards, information sharing, and adapting existing processes for awardees and applicants.

Board members expressed interest in what PCORI is hearing from awardees on how COVID-19 is affecting their research and other projects, and how PCORI is helping address the impact.

**COVID-19 Response Update**

- Progress on COVID-19 Targeted PFA
  - Consider for Approval – alternative review and approval framework for awards under this PFA
- Nakela Cook, MD, MPH and Jason Gerson, PhD, Senior Program Officer, Clinical Effectiveness and Decision Science (CEDS)

Dr. Gerson began the presentation by providing a brief update on PCORI’s COVID-19 Targeted Funding Announcement. On April 1, 2020, the Board approved $30M for funding new research studies, dissemination and implementation projects, engagement projects, and projects using PCORnet. Now, PCORI plans to release a targeted research funding announcement on May 5, 2020 with 3 priority areas:
  1. Adaptations to Healthcare Delivery
  2. Impact of COVID-19 on vulnerable populations
  3. Impact of COVID-19 on healthcare workforce well-being, management, and training

Next, Dr. Cook provided some details on the accelerated timeline for this PFA. She explained that unlike others, this targeted PFA will not require an LOI from applicants and will receive expedited programmatic screening and merit review. The timeline for this award is as follows:

- Preannouncement released 4/21/20
- PFA opens 5/5
- Applications due 5/26
- Merit Review on 6/23
• Selection Committee on 6/30
• If needed, a Board meeting would be scheduled in early July.
• The maximum project duration is 2 years, with primary outcomes reported within 12 months.

Given the expedited timeline relating to this PFA, Dr. Cook provided the Board with three alternative approval options for awards under this solicitation:
• Option 1: The Selection Committee approves slates of awards from the COVID-19 PFA
• Option 2: The Executive Director approves slates of awards from the COVID-19 PFA after receiving recommendations from the Selection Committee.
• Option 3: The Board of Governors approves slates of awards from the COVID-19 PFA after receiving recommendations from the Selection Committee.

Board discussion focused on:
• A general preference for Option 2
• A need for timely decisions for awards under this PFA
• The possibility of adding more Board members to the Selection Committee for review of these awards
• The opportunity for this new approval framework to inform the Board’s approval alternatives for slates of awards in the future
• The Executive Director’s role in Option 1 vs Option 2
• The expertise of the Selection Committee and PCORI Science Staff to make informed decisions regarding the selection of these awards

Cook and Gerson confirmed that applications will still undergo a rigorous merit review with external subject-matter experts. PCORI’s merit review team is already identifying reviewers with expertise in relation to COVID-19. PCORI’s secondary programmatic review would only look for the application’s alignment with the PFA’s goals and PCORI’s portfolio and priorities. Regarding the Executive Director’s role in Option 1 vs Option 2, Dr. Cook noted that the Executive Director would be kept informed of developments under Option 1 but would not conduct any pre-approvals or screenings of applications.

The following motion was made by Grayson Norquist and seconded by Gail Hunt.
Obtained via FOIA by Judicial Watch, Inc.

Motion: That the Board approve:

• That the Executive Director be authorized to approve slates of awards in FY20 recommended for funding by the Selection Committee from the COVID-19 PFA, consistent with the Board-approved funding commitment relating to COVID-19 projects (Option 2 above)

Approved by a majority vote of the voting Board members by roll call vote (15 in favor, 0 opposed; 0 abstained; 0 recusals). Jennifer DeVoe and Janet Woodcock were not present during this vote.

Additional COVID-19 Response Updates

• PCORnet HERO Registry and Trial

Josephine Briggs, MD, Acting Chief Science Officer, Christopher Forrest, MD, PhD, Children’s Hospital of Philadelphia; Susanna Naggie, MD, Duke Clinical Research Institute

Dr. Briggs began the update by noting that on April 1, 2020 the Board approved use of the mechanism of a PCORI-issued invitation to submit a proposal for funding of the Healthcare Worker Exposure Response and Outcomes (HERO) Registry and Hydroxychloroquine (HERO-HCQ) Trial and authorized the Executive Director to review, negotiate, and approve funding up to $50 million in total costs. PCORI issued the invitation and ultimately funded a strong application from Adrian Hernandez, MD at Duke University. The study team has assembled a Steering Committee to oversee the HERO Research Program co-chaired by Judith Currier, MD, MSc from the University of California, Los Angeles and Russell Rothman, MD, MPP from Vanderbilt University Medical Center.

Briggs explained that PCORI convened an Advisory Panel to provide advice to the Executive Director about overall funding and monitoring questions and issues related to the HERO Research Program. She explained that the Panel does not serve the function of a Data and Safety Monitoring Board (DSMB) as establishing and overseeing the DSMB is the responsibility of the study sponsor, Duke University.

Next, Briggs discussed the role of the HERO Registry. She explained that the role of the Registry is to facilitate the participation of health care workers (HCWs) as partners in research on COVID-19 issues. She noted that while studies of novel therapies and vaccines are outside of PCORI’s legislative mandate, partnerships with other funders and collaborators on such studies is part of the Registry mandate. Briggs then introduced the Chair of the HERO Registry Sub-Committee, Christopher Forrest, MD, PhD, to provide more information on the Registry design and goals.
Forrest began by noting that the Registry was launched on April 10, 2020 and currently has over 10,000 participants from all 50 states. Forrest echoed Briggs’ remarks by stating that the Registry will not be limited to the HERO-HCQ trial but will facilitate future research opportunities within a community of healthcare workers to evaluate future tools and novel therapies. He explained that the Registry has three objectives including building a community of HCWs, offering participants opportunities to participate in research, and returning results to all participants. Forrest noted that eligibility for the registry is broad and meant to capture anyone over 18 who works in a healthcare facility and can read English or Spanish. He explained that the registry collects core information via periodic surveys to understand COVID-19 exposures and illness, access to personal protective equipment, and HCW concerns and burnout. Forrest also presented preliminary data including demographics, use of Personal Protective Equipment (PPE), concerns on the impact of the pandemic on HCW health and wellbeing, and other concerns about risk to exposure. He concluded his presentation by noting that these early aggregate Registry results will be returned to participants through email, the Registry website, and an interactive Town Hall event.

Next, Briggs addressed the HERO-HCQ trial by explaining why studying hydroxychloroquine (HCQ) remains a priority. She explained that the combination of extensive use of HCQ, combined with weak clinical evidence and safety concerns creates an urgent public health need for definitive studies. Briggs then introduced HERO-HCQ trial co-principal investigator Susanna Naggie, MD. Naggie provided additional background information on HCQ. She explained that HCQ has a long history of use and is widely prescribed with over 5 million prescriptions in the US in 2017. Naggie explained that while no large-scale studies comparing HCQ to other disease-modifying anti-rheumatic drugs (DMARDs) have been conducted, observational studies suggest it is generally safe. Additionally, the American College of Rheumatology identified HCQ as the DMARD with the least contraindications. She also noted that concerns over HCQ safety are regarding chronic usage. She explained that there is an increased risk of cardiovascular events when used in combination with Azithromycin. Naggie also stated that the most common side effects include nausea (at high dose), rash, and retinopathy (with prolonged use).

Naggie noted that there are 15 treatment and 19 prevention studies in ClinicalTrials.gov. She added that there is a lack of
information on the safety or efficacy of HCQ for prevention of COVID-19 in a well population. Naggie explained that the safety of HCW participants is of utmost importance. The HERO-HCQ trial is being conducted under an Investigational New Drug (IND) application with FDA oversight. Additionally, Duke has formed a DSMB for the trial that meets weekly to review safety events and to ensure severe unexpected events are identified and reported to the FDA. Naggie also noted that the HERO-HCQ trial protocol excludes any HCW at high risk for HCQ toxicity including HCW at high risk for QT prolongation, severe skin reactions, retinopathy, severe heart disease, or medications that can interact with HCQ. Briggs concluded the presentation by adding that the oversight and monitoring processes will enable safety and futility issues will be addressed promptly. She also explained that early termination is possible if indicated by either safety or futility. Lastly, Briggs described the rapid timeline for implementation of this study.

After the presentation Goertz, opened the floor to discussion. The Board expressed enthusiasm for the rapid timeline for funding and implementation of the HERO Research Program. Several Board members noted concern regarding the lack of diversity among the initial Registry participants and inquired about strategies being employed to improve the diversity of Registry participants. Forrest explained that initial recruitment efforts were focused on hospitals participating in PCORnet and they are now reaching out to unions and professional societies as well as hospital leadership to get improve representation from those working in other roles in healthcare facilities. It was suggested that specific emphasis should be employees working in senior healthcare facilities and first line responders.

There was also discussion about whether media coverage of HCQ has impacted trial enrollment. Naggie noted that they have not seen an impact yet and have successfully randomized 265 participants in just under two weeks. She also explained that they have created material for study sites to help facilitate discussions with participants. Naggie stated that the expectation for each site is to enroll 300 participants over a four to six-week period. She noted that one site has already enrolled over 150 participants.

Lastly, one Board member noted that the HERO Research Program is an excellent example of why PCORI invested in developing PCORnet. PCORnet was always envisioned as a national resource to help answer important questions.
PCORI is seeking ways to play a leading, meaningful, and responsive role in the national research response to the current threats of the novel coronavirus and COVID-19. On April 1, 2020, the Board approved up to $20M in funding allocation enabling the adaptation of currently funded research and other projects. In response to the Board’s funding allocation, PCORI posted three funding opportunities to seek investigator-initiated proposals to address the COVID-19 public health crisis for active awardees under the Research, Engagement Awards, and Dissemination & Implementation award mechanisms.

These enhancements must serve the original aims of the award and can include modest additions to existing aims and/or be an adjunct project that addresses COVID-19. The review will rely on existing departmental review and approval processes, with an added layer of cross-departmental input, to expedite review and approval of these enhancements. The Executive Director makes the final approval for all funding decisions following input and recommendations at the cross-departmental level. PCORI has already received proposals that offer ways to transform existing funded awards. It is anticipated that these enhancements will begin in mid-May.

Dr. Forsythe presented on the expected effects of the COVID-19 pandemic on PCORI’s award portfolio and the information that will be captured to understand and respond to those effects.

Forsythe shared that the entire research enterprise, including PCORI, has been affected by the pandemic, particularly because of limits on in-person interactions and research activities. Forsythe outlined the metrics PCORI plans to track organized into two groups: those related primarily to the pandemic, and routine metrics part of the quarterly Dashboard that are likely to be affected by the pandemic. Metrics related to the pandemic include indicators about projects PCORI has already funded (e.g., changes to protocols and engagement plans and project delays or terminations related to the pandemic) and projects to be funded specifically to address the pandemic (e.g., quantity and quality of responses to COVID specific funding opportunities, dollars invested in projects to address the pandemic, expected impact of this body of studies). Routine metrics that may be affected include, as an example, the quantity and quality of
response to typical funding announcements and project recruitment success. Forsythe noted that these metrics will capture both the challenges and the opportunities of the pandemic - for example, PCORI may see increased use of PCORnet in the context of the pandemic. Forsythe also noted that PCORI will capitalize on opportunities to learn about ways PCORI may improve its application and review processes going forward, based on efforts to expedite these processes in response to the pandemic.

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<th>Public Comment</th>
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<tr>
<td>- Kristin Carman, MA, PhD, Director, Public &amp; Patient Engagement</td>
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| No members of the public requested the opportunity to make a public comment. Thus, there were no public comments presented during this time. |

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<tr>
<th>Wrap up and Adjournment</th>
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<tbody>
<tr>
<td>- Christine Goertz, DC, PhD</td>
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<tr>
<th>Meeting adjourned at 2:26 pm</th>
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Update on COVID-19 Initiatives and Request for Additional Funding

Nakela Cook, MD, MPH
Executive Director
PCORI has launched a new briefing on COVID-19-related topics that could potentially affect health care in the United States within the next 12 months.

Horizon scanning is a systematic process that serves as an early warning system to inform decision makers about possible future opportunities and threats.

The first scan discusses a home testing kit and the potential repurposing of the drug anakinra for treating patients with COVID-19 who are experiencing acute respiratory distress syndrome and hyperinflammation.
Project Title: Preventing COVID-19 Infections: Healthcare Worker Exposure Response and Outcomes (HERO) Registry and Hydroxychloroquine (HERO-HCQ) Trial Program
Principal Investigators: Adrian Hernandez, MD, MHS; Emily O’Brien, PhD (HERO registry); Susanna Naggie, MD (HERO-HCQ trial)
Awardee Institution: Duke University

**HERO Registry**

- Create a community of healthcare workers (HCWs) who may be at risk of COVID-19 infection
- Identify HCWs interested in engaging in upcoming clinical trials related to COVID-19 and obtain preferences and willingness regarding participation
- Create a dataset of basic clinical and environmental COVID-19 risk factors and clinical and emotional outcomes for analysis
- Recruitment goal for the HERO registry is 100,000 HCWs

**HERO-HCQ Trial**

- Will randomize 15,000 at-risk HCWs into a randomized clinical trial to evaluate the efficacy of hydroxychloroquine (HCQ) to prevent COVID-19 clinical infection in HCWs
- HCWs eligible for the HERO-HCQ trial will work at one of the 40 PCORnet sites participating in the trial
- Secondary aims:
  - To evaluate the efficacy of HCQ to prevent viral shedding of SARS-CoV-2 among HCWs
  - Evaluate safety and tolerability of HCQ
HERO Registry Coverage and Trial Enrollment

**HERO Registry**
- 14,535 participants have signed the registry consent
  - Covers all 50 states

**HERO-HCQ Trial**
- 32 sites activated
- 28 sites have enrolled 918 participants

As of June 15, 2020
Oversight of the HERO-HCQ RCT

- The HERO-HCQ trial oversight mechanisms include the following:
  - Trial conducted under Investigational New Drug Safety FDA requirements
  - Data Safety and Monitoring Board established by the sponsor
    - DSMB is engaged with other DSMBs of large COVID-19 related trials
    - Recommend continuation, revision or discontinuation of protocol
  - Trial subject to Institutional Review Board (IRB) review
  - Monitoring processes assure effectiveness, safety, or futility issues will be addressed promptly
  - Consistent with best practices for RCT oversight, early termination is possible if indicated by either safety or futility
  - PCORI Advisory Panel advises PCORI’s ED about overall funding and monitoring questions and issues
  - PCORI contractual mechanism and processes reduce financial impact of early termination
PCORnet COVID-19 Common Data Model

Background

- PCORnet is working to characterize the cohort of COVID-19 patients and provide detailed information on demographics and pre-existing conditions through weekly queries.

- Purpose:
  - To support CDC surveillance and develop a strategy for longer-term COVID-19 research.

- Approach:
  - PCORnet networks are creating a stand-alone version of the Common Data Model (CDM) that includes a subset of patients with respiratory illness since January 2020.
  - Employing modified workflows to allow data refreshes much faster (days vs 3 months).
  - Query is reissued weekly, so sites have an opportunity to join once they are ready.

- Inclusion criteria:
  - Diagnosis codes for COVID-19.
  - COVID-19 antigen lab codes.

- Query information:
  - Demographics and state.
  - Care setting.
  - Preexisting conditions and prescriptions for or medication administration of drugs of interest.

NIH - 000955

Obtained via FOIA by Judicial Watch, Inc.
COVID-19 Enhancement – Use Cases
Research Ready COVID-19 CDM

- PCORnet Coordinating Center and networks are expanding scope of work to:
  - Add non-CDM data of interest
    - COVID-19+ flag
    - SARS-CoV-2 test results (antigen & antibody)
    - Select medication use: e.g., Remdesivir use (order / administration)
    - Admission to ICU / Use of mechanical ventilation

- Partnership with CDC to support weekly information refresh needed for CDC surveillance activities
  - Broad network participation

- Partnership with Reagan-Udall and the COVID-19 Evidence Accelerator
  - Utilize vanguard sites
  - Optimize and rigorously validate key COVID-19 elements
  - Curate and validate to establish Research Ready Data fit for purpose
  - Proposed use case: treatment and outcomes associated with COVID-19 coagulopathy

- Partnership with NHLBI and NICHD on MIS-C
Posting of COVID-19 PFAs for New Awards

• In May 2020, PCORI posted a COVID-19 **Targeted Funding Announcement** for new research studies, with three priority areas:
  • Adaptations to healthcare delivery
  • Impact of COVID-19 on vulnerable populations
  • Impact of COVID-19 on healthcare workforce well-being, management, and training

• PCORI also posted an **Engagement Award** Special Funding Award Opportunity to support projects that help communities increase their capacity to participate across all phases of the PCOR/CER process, while responding to contextual changes as a result of the COVID-19 pandemic.

• Both PFAs attracted significant interest, received a robust response, and applications are currently under review
Update on Applications Submitted in Response to COVID-19 PFAs for New Awards

• Both COVID-19 PFAs attracted significant interest

• Targeted **Research** Funding Announcement for COVID-19:
  • Hundreds of applications submitted
  • 2 rounds of Merit Review planned

• **Engagement Award** Special Funding Award Opportunity:
  • Robust response, now under review
COVID-19 Targeted PFA: Research Award Examples

• Promising applications propose research on topics that include:
  • Psychological distress among healthcare workers
  • Prevention of COVID-19 in nursing homes
  • Homelessness, supportive housing, and COVID-19
  • Strategies for infection control (e.g., shelter-in-place)
  • Interventions to mitigate impact of COVID-19 among vulnerable/racial minority populations
Update on Enhancements for Currently Funded Projects

- In April 2020, PCORI posted three funding announcements to seek investigator-initiated proposals to address the COVID-19 public health crisis for current awardees in the form of enhancements.
- PCORI has already received a high volume of proposals that offer exciting ways to transform existing funded awards that serve the award’s original aims and result in findings related to COVID-19.
- **Over 150 awards have submitted proposals** for Enhancements to date, with proposals from all award types (Research, D&I, and Engagement).
  - Approved Enhancements total $16.9M to-date:
    - $11.1M in Research Enhancements
    - $2.8M in D&I Enhancements
    - $3.0M in Engagement Enhancements
Funded Enhancements
Total Budget = $20M

Estimated Total Approved Dollars for Enhancements
Last updated: June 12, 2020

- Total: $16,900,838
- Engagement: $3,013,869
- Research: $11,053,030
- D&I: $2,833,939

NIH - 000961
- Funded D&I
- Funded Engagement
- Funded Research
## COVID-19 Enhancements – Current PCORI Funding

<table>
<thead>
<tr>
<th>Health Condition</th>
<th>Cancer</th>
<th>Cardiovascular Diseases</th>
<th>Gastrointestinal Disorders</th>
<th>Genetic Disorders</th>
<th>Infectious Diseases</th>
<th>Mental/Behavioral Health</th>
<th>Muscular &amp; Skeletal Disorders</th>
<th>Neurological Disorders</th>
<th>Nutritional &amp; Metabolic Disorders</th>
<th>Rare Disease</th>
<th>Reproductive &amp; Perinatal Health</th>
<th>Respiratory Diseases</th>
<th>Other or Non-Disease Specific</th>
</tr>
</thead>
<tbody>
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</tr>
<tr>
<td>Research Awards &amp; Intervention Strategy</td>
<td>Drug</td>
<td>Other Clinical</td>
<td>Health Services</td>
<td>Tele-medicine</td>
<td>Training &amp; Education</td>
<td>Screening</td>
<td>Technology</td>
<td>Behavioral Interventions</td>
<td>N/A</td>
<td>Dissemination &amp; Implementation Awards</td>
<td>Engagement Awards</td>
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<td>NIH - 000962</td>
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</table>
A Stakeholder-Driven Comparative Effectiveness Study of Treatments to Prevent Coronary Artery Damage in Patients with Resistant Kawasaki Disease

**Enhancement Research Question**

- Seeks to characterize and compare a significant new pediatric inflammatory condition with similarities to Kawasaki disease (KD) and which has emerged in communities heavily affected by COVID-19. The team will compare clinical data and laboratory samples from three groups of patients: typical KD prior to Covid-19, typical KD during Covid-19, and PIMS patients.

**Potential Impact of Enhancement**

- This will further characterize COVID-related PMIS and offers the opportunity to better understand two rare diseases with significant morbidity.

**Methods**

- Observational study

---

The current award seeks to test the superiority of infliximab to a second intravenous immunoglobulin (IVIG) infusion for treatment of persistent or recrudescent fever in children with KD, who fail to become afebrile after the first IVIG infusion.

Jane Burns, MD

*University of California, San Diego*

*Assessment of Prevention, Diagnosis, and Treatment Options, Awarded December 2016*
Expanding access to the Infusion Center Model for People Living with Sickle Cell Disease (SCD)

Enhancement Activities

- Aims include 1) conducting a robust evaluation of telemedicine on access to care, patient experience and health outcomes for adults with SCD; and 2) assessing barriers and facilitators, potential benefits and risks, and satisfaction with telemedicine visits using semi structured qualitative interviews with adults living with SCD.

Potential Impact of Enhancement

- This enhancement includes an evaluation of telemedicine as a viable option to improve outcomes and broaden access to care for adults living with SCD. If telemedicine proves to be valuable for adults living with SCD, it will be incorporated into the implementation toolkit that is being developed as a component of the original award.

Current award aims to understand the barriers and facilitators to successful implementation of an infusion clinic (IC) model for adults with SCD diverse group of key stakeholders. The objective of this award is to identify the best strategies for broad implementation of the model and develop, test, and evaluate an implementation toolkit.

Sophie Lanzkron, MD, MHS
Johns Hopkins School of Medicine
Capacity Building, Awarded November 2019
Enhancement Activities

- Pediatric outpatient settings have seen a dramatic shift to telehealth. Evidence suggests that antibiotic stewardship is less effective in telemedicine than during in-person visits. This enhancement will adapt educational content for clinicians, audit-and-feedback reports, and practice facilitation to address appropriate antibiotic prescribing for acute respiratory illnesses (ARTIs) during telemedicine visits.

Potential Impact of Enhancement

- Supports national goals for antibiotic stewardship, benefiting the public as well as children with ARTIs, for whom over-prescription of broad-spectrum antibiotics can cause unnecessary side effects such as diarrhea and vomiting. It is of immediate and ongoing relevance for improving outcomes for this target population.

Antibiotics are the most commonly prescribed medication for children, primarily in outpatient settings for treatment of acute respiratory tract infections (ARTIs). Contrary to current guidelines, many children are prescribed broad-spectrum rather than narrow-spectrum antibiotics as first-line treatment. The original D&I projects adapts and implements a tested antibiotic stewardship program to improve outpatient prescribing at 350,000 ARTI visits in diverse practice settings across 5 health systems.
Consider for Approval: Additional Funding for COVID-19-Related Project Enhancements and COVID-19 Targeted PFAs

Nakela Cook, MD, MPH
Executive Director
Background on COVID-19 Funding Approval

• On April 1, 2020, the Board approved up to $110M in total for COVID-19-Related Funding:
  • $50M for the HERO Registry and Trial
  • $20M for COVID-19-related enhancements of currently-funded projects
  • $30M for funding new projects from targeted COVID-19 PFAs
  • $10M for Rapid Response Fund

• In order to be able to fund meritorious proposals without delay we request up to $50M in additional funding for COVID-19-related:
  • Enhancements to currently-funded projects
  • New projects funded via targeted PFAs

NIH - 000967
Rationale for Additional Funding for COVID-19-Related Project Enhancements and Targeted PFAs

- We are requesting up to $50M in additional funding for COVID-19-Related Project Enhancements and the COVID-19 Targeted PFAs for the following reasons:
  - The rapidly-evolving nature of the COVID-19 pandemic
  - High volume of meritorious applications from the research community for new projects
  - High volume of meritorious proposals from our awardees for project enhancements
  - PCORI’s unique position to fund projects that provide answers to the challenging COVID-19 related dilemmas facing patients, caregivers, providers, health systems, and policymakers
Board Vote

Call for a Motion to:

• Approve Up to $50M in additional funding for COVID-19-Related Project Enhancements and Targeted PFAs

Call for the Motion to be Seconded:

• Second the Motion
  • If further discussion, may propose an Amendment to the Motion or an Alternative Motion

Roll Call Vote:

• Vote to Approve the Final Motion
  • Ask for votes in favor, opposed, and abstentions
Targeted PFA
Suicide Prevention: Brief Interventions for Youth

Robert Zwolak, MD, PhD
Chair, Science Oversight Committee

Els Houtsmuller, PhD
Associate Director, Healthcare Delivery and Disparities Research
Suicide Prevention: Topic Selection

Increased rates
Disparities
PCORI BoG
Congressional Black Caucus

Stakeholder Interviews, Meetings, Workshops

Background Research, Literature Reviews; Other Funders

NIH - 000973
Stakeholder Input

American Psychiatric Association
Medicaid Medical Directors
National Institute on Mental Health
    Jane Pearson, Chair, NIMH
Suicide Research Consortium
Grayson Norquist

National Action Alliance for Suicide Prevention
    Colleen Carr, Director
RI International - David Covington
National Academy for State Health Policy

PCORI 2-day stakeholder workshop, December 2019
    People with lived experience, Providers, Payers, Health systems, Researchers

Action Alliance
    Crisis Services conference calls
    Youth Suicide Prevention Stakeholder Meeting
Suicide Prevention Background

- Suicide rates in the US have increased by 35% (10.5 to 14.2 per 100,000) since 1999.
- In 2018, suicide 2nd leading cause of death for ages 10-34.
Suicide Prevention: Youth (15-24)

- Suicide rates for ages 15–24 rose 46% from 1999 to 2018 (9.9 to 14.5 per 100,000)
  - Suicide attempts 10-20 times more frequent
- Rates vary by gender, gender identity, race/ethnicity, state, with higher rates for
  - Females: Suicide attempts
  - Males: Death by suicide
- LGBTQ
- Rural
- American Indian/Alaska Native

- Rates have increased for
  - Black youth
  - Latina youth

NIH - 000976
Suicide Prevention: Clinical Care

Risk Factors • Predictors • Protective Factors

Assessment Suicide Risk

OUTPATIENT

INPATIENT

INTERVENTIONS

Brief Interventions
Psychological Treatments
Medications
Procedures

NIH - 000977
Suicide Prevention: Brief Interventions

• Goal: reduce acute suicide risk, connect to treatment

• Brief

• Variety of settings: Emergence Department, Primary Care, Detention Center, School, Mobile Crisis Unit, Specialty Care, Inpatient care

• Range of healthcare workers (nurses, assistants, counselors)
Brief Interventions: Evidence and Use

- Evidence-based BIs (e.g., Safety Planning, Motivational Interviewing) evaluated primarily in adults
  - Used for general population, including youth

- Some evidence BIs for youth (e.g., Safety Planning with phone follow-up)
  - Reduction suicidality
  - Increased connection to treatment

- Telehealth: COVID 19 and beyond
Brief Interventions: Evidence Gaps

Comparative effectiveness of:

• Brief Interventions for Youth (15-24)
• Tailored approaches to Brief Interventions for youth from vulnerable populations (e.g., Black, Latina, LGBTQ, American Indian/Alaska Native, rural)
• Tailoring may include
  o Involvement of People with Lived Experience
  o Telehealth (app, text-based, web-based, phone calls, video calls)
  o Cultural (Language, Family involvement, Rituals)
  o Specific setting (e.g., Primary Care, School, Home, Community)
Research Question: What is the comparative effectiveness of different Brief Interventions to reduce suicidality and improve outcomes for youth age 15-24?

- Particular interest in tailored approaches for subpopulations with increased rates of suicidality (LGBTQ, American Indian/Alaska Native, Black, Latina, rural)
### Brief Interventions to Reduce Suicidality and Improve Outcomes for Youth at Increased Risk for Suicide

<table>
<thead>
<tr>
<th>Population</th>
<th>Youth (15-24) requiring intervention but not continuous monitoring based on clinical assessment</th>
</tr>
</thead>
</table>
| Intervention | Brief Interventions used for adolescent populations (e.g., Safety Planning, Motivational Interviewing)  
Tailored Brief Interventions; tailoring should be specific to target population(s). |
| Comparator(s) | Head to Head; Brief Interventions or Tailored Brief Interventions |
| Outcomes | Primary: Suicidal ideation, self harm, engagement in mental health care  
Secondary: functional measures, school participation, employment, skills to manage suicidality, connectedness, quality of life, healthcare utilization (hospital or ED use) |
| Timing | Up to 12 month follow-up |
| Setting | Primary care, emergency care, schools, mobile crisis unit, community-based settings where youth may receive crisis or mental health care, home, inpatient care, juvenile detention center |
Requested Research Commitment

- Total requested for this PFA is $30M in total costs
- Estimated number of studies: 2-4
- Maximum project duration: 5 years
Board Vote

Call for a Motion to:
• Approve the development and release of "Suicide Prevention: Brief Interventions for Youth" Targeted PFA

Call for the Motion to be Seconded:
• Second the Motion
  • If further discussion, may propose an Amendment to the Motion or an Alternative Motion

Roll Call Vote:
• Vote to Approve the Final Motion
  • Ask for votes in favor, opposed, and abstentions
Broad PFAs
Cycle 3 2019 Award Slate

Barbara McNeil, MD, PhD
Chair, Selection Committee

Stanley Ip, MD
Interim Program Director, CEDS

Steven Clauser, PhD, MPA
Program Director, HDDR
## Cycle 3 2019 – Broad PFAs
### Merit Review Criteria

<table>
<thead>
<tr>
<th>Broad PFAs (excluding Methods)</th>
<th>Improving Methods for Conducting Patient-Centered Outcomes Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Potential for the study to fill critical gaps in evidence</td>
<td>1. <strong>Study identifies critical methodological gap(s) in PCOR/CER</strong></td>
</tr>
<tr>
<td>2. Potential for the study findings to be adopted into clinical practice and improve delivery of care</td>
<td>2. <strong>Potential for the study to improve PCOR/CER methods</strong></td>
</tr>
<tr>
<td>3. Scientific merit (research design, analysis, and outcomes)</td>
<td>3. Scientific merit (research design, analysis, and outcomes)</td>
</tr>
<tr>
<td>4. Investigator(s) and Environment</td>
<td>4. Investigator(s) and Environment</td>
</tr>
<tr>
<td>5. Patient-centeredness</td>
<td>5. Patient-centeredness</td>
</tr>
<tr>
<td>6. Patient and stakeholder engagement</td>
<td>6. Patient and stakeholder engagement</td>
</tr>
</tbody>
</table>
Cycle 3 2019 – Broad PFAs
Process Overview

- 176 Letters of Intent (LOIs) received
- 91 LOIs invited to submit a full application
- 70 applications were received
- The Selection Committee is proposing to fund 10 applications* out of 70 received applications

*Recommended by the Selection Committee on June 12, 2020
## Cycle 3 2019 – Addressing Disparities
Slate of 3 Recommended Projects

<table>
<thead>
<tr>
<th>Project Title</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Comparative Effectiveness of Individual Versus Group-level Interventions to Reduce HIV Risk among African Immigrant Women</strong></td>
</tr>
<tr>
<td>Diabetes Medical Nutrition Therapy in Southeastern African American Women</td>
</tr>
<tr>
<td><strong>Online Cognitive Behavioral Therapy for Depressive Symptoms in Rural Patients with Coronary Heart Disease</strong></td>
</tr>
</tbody>
</table>

Resubmissions in bold

NIH - 000990

Obtained via FOIA by Judicial Watch, Inc.
## Project Title

Addressing Anxiety among Low-Risk Chest Pain Patients in the Emergency Department Setting
<table>
<thead>
<tr>
<th>Project Title</th>
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<tbody>
<tr>
<td>Elders Preserving Independence in the Community (EPIC)</td>
</tr>
<tr>
<td>Comparing the Effectiveness of Two Approaches to Preventing Severe Hypoglycemia</td>
</tr>
<tr>
<td>Comparing Fingerstick Blood Glucose Monitoring versus Continuous Glucose Monitoring in Primary Care</td>
</tr>
<tr>
<td>Comparative Effectiveness Trial of Perioperative Telemonitoring for Functional Recovery and Symptoms</td>
</tr>
</tbody>
</table>
# Cycle 3 2019 – Improving Methods for Conducting PCOR

Slate of 2 Recommended Projects

<table>
<thead>
<tr>
<th>Project Title</th>
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</thead>
<tbody>
<tr>
<td><strong>Missing Data When Transporting Treatment Effects from Clinical Trials to a</strong></td>
</tr>
<tr>
<td><strong>Target Population</strong></td>
</tr>
<tr>
<td><strong>An Efficient Distributed Learning Framework for Integrating Evidence in</strong></td>
</tr>
<tr>
<td><strong>Clinical Research Networks</strong></td>
</tr>
</tbody>
</table>

Resubmissions in bold

NIH - 000993
# Cycle 3 2019

## Recommended Slate of 10 Projects

<table>
<thead>
<tr>
<th>PFA</th>
<th>Amount Budgeted</th>
<th>Proposed Total Award*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle 3 2019 Broad</td>
<td>$15M</td>
<td>$24.9M</td>
</tr>
</tbody>
</table>

*All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.*
Board Vote

Call for a Motion to:

• Approve funding for the recommended slate of awards from the Cycle 3 2019 Broad PFAs

Call for the Motion to be Seconded:

• Second the Motion
  • If further discussion, may propose an Amendment to the Motion or an Alternative Motion

Roll Call Vote:

• Vote to Approve the Final Motion
  • Ask for votes in favor, opposed, and abstentions
Limited Competition: Dissemination and Implementation PFA
Implementation of PCORI-Funded Patient-Centered Outcomes Research Results
Cycle 3 2019 Award Slate

Lawrence Becker
Chair, Engagement, Dissemination, and Implementation Committee (EDIC)

Joanna Siegel, SM, ScD
Director, Dissemination and Implementation Program

NIH - 000998
# Merit Review Criteria

**Limited Competition PFA**

1. Importance of research results in the context of the existing body of evidence
2. Readiness of the research results for implementation
3. Technical merit of the proposed implementation project
4. Project personnel and environment
5. Patient-centeredness
6. Patient and stakeholder engagement
• 11 Letters of Intent (LOIs) submitted
• 7 LOIs invited to submit a full application
• 6 applications received

Proposed funding slate is recommended by the Engagement, Dissemination, and Implementation Committee (EDIC)
• Proposing to fund 1 applications out of the 6 received
• Funding rate is 17 percent
<table>
<thead>
<tr>
<th><strong>Project Title</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementing Best-Practice, Patient-Centered Venous Thromboembolism Prevention in Trauma Centers</td>
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</tbody>
</table>
**Cycle 3 2019 - Limited Competition Dissemination and Implementation PFA**

Slate of 1 Recommended Project

<table>
<thead>
<tr>
<th>PFA</th>
<th>Amount Budgeted [per Year]</th>
<th>Proposed Total Award*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation of PCORI-Funded Patient-Centered Outcomes Research Results</td>
<td>$9.0M</td>
<td>$1.4M</td>
</tr>
</tbody>
</table>

Note: Budgeted amount is for up to 3 cycles per year; $6.1M awarded during first two cycles of 2019.

* All proposed projects, including requested budgets and project periods, are approved subject to a programmatic and budget review by PCORI staff and the negotiation of a formal award contract.
Board Vote

Call for a Motion to:

- Approve funding for the recommended slate of awards from the Cycle 3 2019 Limited Competition Implementation of PCORI-Funded Patient-Centered Outcomes Research Results PFA

Call for the Motion to Be Seconded:

- Second the Motion
  - If further discussion, may propose an Amendment to the Motion or an Alternative Motion

Roll Call Vote:

- Vote to Approve the Final Motion
  - Ask for votes in favor, opposed, and abstentions

NIH - 001003
Dashboard Review
Second Quarter of FY-2020

Nakela Cook, MD, MPH
Executive Director
PCORI Board of Governors Dashboard
Second Quarter FY-2020 (As of 3/31/2020)

Funds Committed

<table>
<thead>
<tr>
<th>Budgeted</th>
<th>Actual</th>
</tr>
</thead>
<tbody>
<tr>
<td>$155M for FY-2020</td>
<td>Q1 Q2</td>
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</table>

Operational Expenses

<table>
<thead>
<tr>
<th>Budgeted</th>
<th>Actual</th>
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<tbody>
<tr>
<td>$84M for FY-2020</td>
<td>Q1 Q2</td>
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</table>

Research Project Performance

<table>
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<tr>
<th>% of Research Projects On Track</th>
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<tr>
<td>Pre-COVID Impact</td>
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<tr>
<td>Q1 Q4 Q1 Q2</td>
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</table>

Dashboard Key

- Q3 2019
- Q4 2019
- Q1 2020
- Q2 2020
- Meeting Target
- Not Meeting Target
- Needs Board Attention
- Target in Development or Not Applicable

Results Published in Literature

<table>
<thead>
<tr>
<th>Articles</th>
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<tbody>
<tr>
<td>CER Results and Other Results Published in the Literature</td>
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<tr>
<td>Q3 Q4 Q1 Q2</td>
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</tbody>
</table>

Altmetric: Attention to PCORI Results

<table>
<thead>
<tr>
<th>% of CER Results Publications in Top 10% of Attention</th>
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<tbody>
<tr>
<td>Q3 Q4 Q1 Q2</td>
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Speed of PCORI Peer Review

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<tr>
<th>Months</th>
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<tbody>
<tr>
<td>Median Time to Complete Peer Review (Grey = 75th Percentile)</td>
</tr>
<tr>
<td>Q3 23</td>
</tr>
<tr>
<td>Q4 20</td>
</tr>
<tr>
<td>Q1 18</td>
</tr>
<tr>
<td>Q2 21</td>
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</tbody>
</table>

Results Viewed on PCORI.org

<table>
<thead>
<tr>
<th>Page Views</th>
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<tbody>
<tr>
<td>Average Pageviews of Results Posted to PCORI.org</td>
</tr>
<tr>
<td>Q3 Q4 Q1 Q2</td>
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</tbody>
</table>

Front Door Requests to PCORnet

<table>
<thead>
<tr>
<th>Requests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Front Door Requests Submitted to PCORnet</td>
</tr>
<tr>
<td>Q3 Q4 Q1 Q2</td>
</tr>
</tbody>
</table>
A Completed PCORI-Funded Study, From Results to Impact

Example: Using Wellness Coaches and Extra Support to Improve the Health and Wellness of Adults with Serious Mental Illness

Principal Investigator: James M. Schuster, MD, MBA, UPMC Center For High-Value Health Care

Dr. Schuster is also the Chief Medical Officer for Medicaid, Special Needs, and Behavioral Services and Vice President of Behavioral Integration at UPMC Insurance Services Division

Study Title: Optimizing Behavioral Health Homes by Focusing On Outcomes That Matter Most for Adults with Serious Mental Illness

1. Results: Results published in Health Affairs; Results summaries posted to PCORI.org; Final Research Report

2. Uptake: Statewide implementation; citation in systematic reviews; use by external authorities

3. Further Funding for Dissemination and Implementation: PCORI-funded Implementation Project; PCORI-funded Engagement Dissemination project

NIH - 001012
PCORI-Funded Study Results

Publication: A behavioral health home model is a best-practice solution to addressing health needs of adults with serious mental illness

**Summary:** People with serious mental illness like bipolar disorder or schizophrenia often don't receive the physical health care they need. Community mental health centers can help people with serious mental illness manage their health and prevent later health problems.

**This study compared the effectiveness of two behavioral health home approaches:** wellness coaching plus a provider-supported integrated approach vs. a self-directed approach on patient activation in care, health status, and engagement in primary or specialty care among adults with serious mental illness. Patients were eligible to participate if they were Medicaid-enrolled and were receiving services at community mental health centers (CMHCs).

The study found that **both approaches significantly increased patient activation in care** (more quickly in provider-supported care), engagement in primary and specialty care, and perceived mental health status. The success of this behavioral health home intervention in improving important outcomes and the use of novel diffusion strategies has also led to its **uptake by forty-three additional providers across Pennsylvania.**
Results Summaries: The PCORI Translation Center prepares summaries of findings from each of PCORI’s studies once the findings have been peer-reviewed. Two summaries, one for the general public and one for healthcare professionals, present results in clear language that has been tested with each audience. PCORI posts these summaries to PCORI.org within 90 days after accepting the final results of the study, as required by our authorizing law.

Results Summary for the General Public

Using Wellness Coaches and Extra Support to Improve the Health and Wellness of Adults with Serious Mental Illness

Principal Investigator
James M. Schuster, MD, MBA

Organization
UPMC Center for High-Value Health Care

What was the research about?
People with serious mental illness like bipolar disorder or schizophrenia often don’t receive the physical health care they need. Community mental health centers can help people with serious mental illness manage their health and prevent later health problems.

- Involvement in their health care
- Depression
- Quality of life
- Satisfaction with their care

Professional Abstract Results Summary

Objective
To compare the effectiveness of two interventions—wellness coaching plus a provider-supported integrated approach or a self-directed approach—on patient activation in care, health status, and engagement in primary or specialty care among adults with serious mental illness receiving services at community mental health centers (CMHCs).

Study Design

<table>
<thead>
<tr>
<th>Design Element</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>Randomized controlled trial</td>
</tr>
<tr>
<td>Population</td>
<td>1,229 adults with serious mental illness who had Medicaid and received care at 11 participating CMHCs</td>
</tr>
</tbody>
</table>
| Interventions/Comparators | Wellness coaching plus provider-supported integrated care
|                   | Wellness coaching plus patient self-directed care |

NIH - 001014
Final Research Report (FRR): The comprehensive, final peer-reviewed report of the funded study, usually equivalent to the length and content of 3-5 journal articles, which is posted to the project page.

The FRR for the results of this study is a 69-page, open-access write-up of the study, including detailed methods, results, tables, and figures.

Uptake into Systematic Reviews: Results from this study have been cited in one Systematic Review to-date:

The intervention, the expanded Behavioral Health Home Program was recognized by Substance Abuse and Mental Health Services Administration (SAMHSA) for Excellence in Wellness in 2016.

2016 Recognition winners were those that created meaningful improvements in the lives of people in recovery from mental and/or substance use disorders, and effectively worked to address the increased rates of chronic illness and premature death experienced by people in recovery from behavioral health disorders (source).

The Behavioral Health Alliance of Rural Pennsylvania (BHARP)'s Behavioral Health Home Plus Pennsylvania

NIH - 001017

Engagement Award for Dissemination: PCORI's Engagement Award: Dissemination Initiative gives organizations and communities the opportunity to spread awareness and increase knowledge of evidence from PCORI-funded research that is targeted directly to patients, clinicians, and others who can use this information to inform healthcare decisions.

**Title:** Helping Adults with Serious Mental Illness Improve Their Health and Wellness

**Project Lead:** Alise Gintner, LCSW

In this project, Rochester Regional Health (RRH) will address the knowledge gap among patients and providers around the inadequacies in medical care for patients with a serious mental health diagnosis, providing a foundation for implementing interventions found effective in James Schuster's PCORI-funded study for improving overall health outcomes in this population.

Working with behavioral health staff and patients, the project will create training curricula, develop toolkits, facilitate training workshops, and build IT infrastructure that will allow behavioral health providers to assign a self-study digital education curriculum for patients to access at home.

The project's goal is for practitioners and patients to have an increased understanding of how these interventions can improve patient activation in care, mental and physical health status, and engagement in primary/specialty care, and to provide them with the tools and motivation to implement these practices into treatment and help lead healthier lives.

[Link to project summary](https://www.pcori.org/research-results/2019/helping-adults-serious-mental-illness-improve-their-health-and-wellness)
**Implementation Project:** PCORI funds implementation projects that incorporate active, multicomponent strategies that will lead to uptake and integration of PCORI-funded evidence into real-world practice settings

- **Title:** Utilizing a Learning Collaborative Approach to Support Behavioral Health Home Dissemination

- **Principal Investigator:** James M. Schuster, MD, MBA, UPMC Center for High-Value Health Care

- This is an implementation project to bring Behavioral Health Home Plus (BHHP), to **two new behavioral health settings:** adult opioid treatment programs, and youth residential treatment centers that treat emotional, behavioral, and substance use issues. The team is working with leaders at each location to train staff, adapting materials used in BHHP, including a guide for providers on how to combine physical and behavioral care, provider trainings, and educational materials.

- To evaluate the project, the team is looking at how clinics are implementing BHHP. Using clinic records, they are tracking whether service users' use of health care changes after BHHP is implemented. They are also tracking whether service users are assisted by providers to set wellness goals, and if they become more confident in taking care of their health.

*Source: [PCORI](https://www.pcori.org).*
Uptake: The intervention, the Expanded Behavioral Health Home Program (BHHP), was adopted statewide by 61 provider organizations in 27 counties in Pennsylvania.

- 40 adult community behavioral health clinic sites
- Adolescent providers:
  - 3 community behavioral health clinic sites
  - 8 school-based sites

NIH - 001020
Economic Impact: Behavioral Health Home Approaches Can Produce Health Care Savings

In a recent analysis published in *Psychiatric Services*, the research team shared findings on the economic impact of the two behavioral health (BHH) home approaches on cost and utilization outcomes. The team used Medicaid claims data to compare utilization (including behavioral health, general medical, and pharmacy claims) from individuals in the study sample to a matched comparison cohort.

**Key Findings:** Relative to a comparison cohort, both models of behavioral health homes achieved:

- **Reduction in overall cost** (15% for provider-supported care and 26% for self-directed care)
- **Increase in use of outpatient general medical services** (43% for provider-supported care and 29% for self-directed care) and a reduction in use of inpatient services

Between the two approaches, provider-supported care (vs. self-directed care) resulted in a larger reduction in general medical inpatient series (28%) and greater reduction in overall cost (26%).

This study showed that implementation of health homes in community mental health provider settings may also produce health care savings and more efficient health care utilization. Similar approaches may be advantageous for individuals with other complex chronic conditions.


(Independent analysis; not funded by PCORI)
Goal 3: Influence the Way Research is Done
Three Examples Highlighted

• Use of PCORI Methodology Standards & Development of Infrastructure and Resources to Promote PCOR
  • PCORI is credited with inspiring and informing the AHRQ-funded ENACT R25 program

• Development of Infrastructure or Resources to Promote/Support PCOR
  • PCORI is credited with inspiring the Children and Youth with Special Health Care Needs National Research Network’s compensation guides for researchers and research partners

• Endorsement, Promotion, and Dissemination of PCORI work
  • PCORI is credited with inspiring engagement practices within the Dissemination and Implementation Science field
Goal 3: Influence the Way Research is Done
Use of PCORI Methodology Standards & Development of Infrastructure and Resources to Promote PCOR

The AHRQ-funded **Expanding National Capacity in PCOR through Training** (ENACT) R25 program, led by PCORI Methods Program awardee, Dr. Douglas Landsittel, builds the methodological skills and research capacity of investigators from minority-serving institutions to design and analyze effective PCOR and CER.

ENACT training content and experiential learning is inspired and informed by PCOR:
- PCORI Methodology Standards and Academic Curriculum
- Results of PCORI methods projects from Dr. Landsittel and others
- Approaches to stakeholder engagement

The program is nurturing novel collaborations among institutions with common and unique strengths and challenges, building a diverse and well-trained PCOR community.

> “We don’t want to reinvent the wheel, there’s already a lot out there about PCOR...The PCORI academic curriculum for the Methodology Standards is one of the biggest things that we cite.”

Douglas Landsittel, PhD; University of Pittsburgh, Department of Biomedical Informatics [March 2020]
PCORI is credited with inspiring the Children and Youth with Special Health Care Needs National Research Network’s compensation guides for researchers and research partners.

PCORI’s Engagement Rubric, Budgeting for Engagement Activities, and Compensation Framework inspired CSYHCNet’s creation of more tailored compensation guides meeting their needs for:

- Youth and family research partners
- Researchers

CSYHCNet compensation guides now shared with other institutions:

- Lucille Packard Foundation, American Academy of Pediatrics, including the Pediatric Research in Office Settings program, American Board of Pediatrics, and others

Involving youth and families as partners in research studies is a concept that has been promoted by family and community organizations...like the Patient-Centered Outcomes Research Institute...Organizations such as these have determined that involving youth and families in research studies as partners makes the research more meaningful to all stakeholders and improves the quality of the end product.

- from CSYHCNet’s Partnering with Youth & Families in Research: A Standard of Compensation

Charlene Shelton, RN, MA, MPA, PhD; CSYHCNet [October 2019]
PCORI is credited with inspiring engagement practices within the Dissemination and Implementation Science field

There has been a strong encouragement to meaningfully engage patients and community stakeholders in research from PCORI, NIH, and other organizations ... We hypothesize that this increase [in stakeholder engagement] may be due in part to the intervening impact of PCORI and other patient-centered funders requiring stakeholder engagement for funding.
• In addition to focusing on any Dashboard items that are noteworthy, off target, or in need of attention, we provide a consistent in-depth focus in each quarter for items that are top priority.
Section 1

Funds Committed to Research

Section Highlights

- In Q2, $39M was committed to Research, Infrastructure, D&I, and Engagement
- Cycle 1 2019 slates, and other award commitments were all On Track for Q2
- In-depth focus in Q4

Funds Committed

<table>
<thead>
<tr>
<th></th>
<th>Budgeted</th>
<th>$155M for FY-2020</th>
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<tr>
<td>Q1</td>
<td>0</td>
<td>25</td>
</tr>
<tr>
<td>Q2</td>
<td>75</td>
<td>100</td>
</tr>
</tbody>
</table>

$ Millions
We are tracking funds committed to Research, Research Infrastructure, Dissemination and Implementation, and Engagement Awards in FY-2020; Quarterly estimates are subject to mid-year updates.

Progress on 2020 Commitment Targets
FY-2020 Budget: $155M Total Commitments

As of Q2-20, PCORI
Committed 105% of the amount budgeted as of Q2 (year to date)
(Target: >90%)

Dashboard Status: Meeting Target
- Cycle 2 2019 Broad slate, Cycle 1 2019 slate additions, and other award commitments were all On Track for Q2
**Funds Committed**

FY-2020 Budget: $155M Total Commitments

We are tracking funds committed to Research, Research Infrastructure, Dissemination and Implementation, and Engagement Awards in FY-2020

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
<th>Q2-20 Projected ($M)</th>
<th>Q2-20 Actual ($M)</th>
<th>Q2-20 % of Projected</th>
<th>Year to Date % of Projected</th>
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</thead>
<tbody>
<tr>
<td>Research</td>
<td>Cycle 2 2019 Broad Slate</td>
<td>$15.0</td>
<td>$16.4</td>
<td>109%</td>
<td>Research: 108%</td>
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<tr>
<td>Research</td>
<td>Cycle 1 2019 Broad Slate Additions</td>
<td>$9.6</td>
<td>$9.6</td>
<td>100%</td>
<td></td>
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<tr>
<td>Research</td>
<td>Cycle 1 2019 Targeted: Age-Related Hearing Loss Addition</td>
<td>$2.6</td>
<td>$2.6</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Research</td>
<td>Evidence Synthesis Awards and Products</td>
<td>$0.1</td>
<td>$0.1</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Infrastructure</td>
<td>PCORnet Coordinating Center Extension</td>
<td>$6.0</td>
<td>$6.1</td>
<td>101%</td>
<td>Infrastructure: 101%</td>
</tr>
<tr>
<td>D&amp;I</td>
<td>Cycle 2 2019 Limited D&amp;I PFA</td>
<td>$3.5</td>
<td>$3.5</td>
<td>100%</td>
<td>D&amp;I: 90%</td>
</tr>
<tr>
<td>D&amp;I</td>
<td>D&amp;I Commitments (Translation Center, Economic Impact Analyses, Emerging Technologies)</td>
<td>$1.8</td>
<td>$0.7</td>
<td>39%</td>
<td></td>
</tr>
<tr>
<td>Engagement</td>
<td>Engagement Awards</td>
<td>$0</td>
<td>$0</td>
<td>N/A</td>
<td>Engagement: 100%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>$38.6</strong></td>
<td><strong>$39.0</strong></td>
<td><strong>101%</strong></td>
<td>Overall: 105%</td>
</tr>
</tbody>
</table>

As of Q2-20, PCORI Committed 105% of the amount budgeted as of Q2 (year to date) (Target: >90%)
Research Funding
Funds Awarded Over Time (Quarterly)

Funds Committed to Research

- Cumulative
  - Broad $960 M
  - Pragmatic $493 M
  - Targeted $593 M

<table>
<thead>
<tr>
<th>FY 2013</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
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<td>20</td>
<td>41</td>
<td>23</td>
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<td>FY 2014</td>
<td>30</td>
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<td>62</td>
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<td>FY 2015</td>
<td>122</td>
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<td>FY 2017</td>
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<td>FY 2018</td>
<td>152</td>
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<td>10</td>
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</tr>
<tr>
<td>FY 2019</td>
<td>51</td>
<td>51</td>
<td>38</td>
<td>40</td>
</tr>
<tr>
<td>FY 2020</td>
<td>32</td>
<td>32</td>
<td>23</td>
<td>3</td>
</tr>
</tbody>
</table>

NIH - 001030
Research Infrastructure Funding
Funds Awarded Over Time (Quarterly)

Funds Committed to Research Infrastructure

- PCORnet Infrastructure $357M
- Learning Health Systems $30M

PCORnet Networks
- Phase I Coordinating Center: FY 2013 Q2 - $94M
- Phase II Coordinating Center: FY 2015 Q1 - $142M
- AHRQ Learning Health Systems: FY 2017 Q4 - $30M
- Patient-Centered Research Foundation (PCRF): FY 2018 Q1 - $16M

- Network Expansion (PCRF): FY 2019 Q1 - $4.4M
- PPRN Engagement Awards: FY 2020 Q1 - $1.5M
- Coordinating Center Extension: FY 2020 Q4 - $6M

NIH - 001031
Dissemination and Implementation Funding
Funds Awarded Over Time (Quarterly)

Funds Committed to Dissemination and Implementation Awards

Limited Competition Awards: Implementation of research results from PCORI-funded studies

Shared Decision Making Awards: Implementation of effective SDM approaches in practice settings

Major Research Investments: Implementation of high-priority PCORI initiatives in the context of the body of related evidence

Cumulative
- Limited Competition $22.3M
- Shared Decision Making $12.2M
- Major Research Investments: $2.5M

Does not include all D&I Commitments (Such as PCOR Translation Center, Horizon Scanning, Impact Assessments, Emerging Technology Reports)
In March 2020, the FAC updated the target, which is now 10% of projected expenses to be measured at the end of the fiscal year. The Dashboard provides quarterly updates, and now reflects the 10% target.

Variance was more than 10% of projected expenses, the threshold for targets set by the FAC. This is mostly due to lower than projected administrative expenses, engagement and science program expenses.
Section 2
Project Performance

Section Highlights
- We are actively managing 330 research projects that are not yet complete
- 93% of projects are On Track; However, Q2 data reflects pre-COVID impact
- In-depth focus in Q3, including data on the impact of COVID-19 on our portfolio

Research Project Performance:
- % of Research Projects On Track
- Q3, Q4, Q1, Q2
Status of PCORI-Funded Research Projects

Current Status of PCORI-Funded Research Projects
N=666, as of Q2-20

- 15 Awarded; Contract Pending
- 16 Too early for quarterly project evaluation or MOU
- 229 Eligible for quarterly project evaluation
- 9 Undergoing Pre-Review Edits
- 36 In PCORI Peer Review
- 25 Summaries being developed for posting
- 328 Complete; Results posted to PCORI.org
- 8 Terminated

See Section 3 for more details on PCORI Peer Review

*Includes CER studies, Methods studies, Pilot Awards, Rapid Cycle Research, and Evidence Synthesis Projects
*Does not include Infrastructure or D&I awards
*Does not include studies awarded in Q3-2020

NIH - 001035

Obtained via FOIA by Judicial Watch, Inc.
We actively monitor our projects, support them to be successful, and classify their progress according to this scale:

<table>
<thead>
<tr>
<th>GREEN</th>
<th>YELLOW</th>
<th>ORANGE</th>
<th>RED</th>
</tr>
</thead>
</table>

**GREEN**
- The Project is meeting >85% of milestones on time
- AND
- Recruitment occurring on schedule, at expected rate
- AND
- PO judges that the project has a high probability of meeting its objectives as planned. PO judgment is based on close review of study progress, including recruitment status.

**YELLOW**
- Project does not meet all criteria for “Green”
- AND
- Project is meeting >65% of milestones on time.
- OR
- Recruitment is ≤75% and >50% of target accrual
- OR
- PO has concerns that without remediation efforts the project will not be able to meet objectives within project period.

**ORANGE**
- Project does not meet all criteria for “Yellow”
- AND
- Project is meeting >50% of milestones on time.
- OR
- Recruitment is ≤50% of target accrual
- OR
- PO has concerns that the project will not meet objectives within the approved project period. Modifications to the Milestone Schedule and/or project plan are likely required.

**RED**
- Project does not meet all criteria for “Orange”
- AND
- Project is meeting <50% of milestones on time.
- OR
- Recruitment is persistently and significantly ≤50% of target
- OR
- PO has significant concerns that the project cannot meet its original objectives. Major modifications to Milestone Schedule are required for the project to be completed.

**Next Steps**

- Continue monitoring project through active portfolio management and per SOPs.
- Increased communication with the PI to monitor and assist with getting the project back on track.
- Placed Under Review at PCORI to determine if it is able to meet its original project plan.
- Pursue modifications to project plan or milestone schedule as appropriate.
- Project Remediation Plan (PRP) memo sent to PI with a 30-day completion date deadline.

NIH - 001036

Inform Leadership of Status
The majority of our projects are on track, and we give more attention to those that are behind schedule.

**Projects On Track**

- **By Number and Percentage**

  - **On Track (Green & Yellow):**
    - Q3: 237
    - Q4: 220
    - Q1: 228
    - Q2: 212
  - **Off Track (Orange & Red):**
    - Q3: 18
    - Q4: 17
    - Q1: 17
    - Q2: 17
  - **Percent On Track:**
    - 100%
    - 80%
    - 60%
    - 40%
    - 20%
    - 0%

**Dashboard Status: Meeting Target**

- With 93% of projects on track, we are above the target of >90% of research projects on track.

Q2 data reflects pre-COVID impact; More on COVID impact will be shared in Q3 Dashboard.
Status of PCORI-Funded Research Projects

We are monitoring trends and shifts in project status (most recent 8 quarters shown)

Project Status by Color Zones
Q3-18 to Q2-20

- Green Zone
- Yellow Zone
- Off Track (Orange/Red)

Q2 data reflects pre-COVID impact; More on COVID impact will be shared in Q3 Dashboard
Status of PCORI-Funded Research Projects
Subset of Projects in the Orange or Red Zone

Percent of Projects Off Track: Details
(Among All Projects Eligible for Color Evaluation)

- Q3-19 (N=255)
- Q4-19 (N=237)
- Q1-20 (N=245)
- Q2-20 (N=229)

- 7% Projects in the Orange or Red Zone
- 2% First Time in Orange or Red
- 5% Consecutively in Orange or Red Zone (3+ quarters)
- <1% Letter of Concern Sent
- <1% Award Terminated

When "Off Track" projects receive an extension, they are not immediately moved out of the Orange/Red zone.

A project will only move to Green or Yellow when they demonstrate they are back on track.

Q2 data reflects pre-COVID impact; More on COVID impact will be shared in Q3 Dashboard.
**Contract Modifications**

**Q2-20 Update**

---

**Contract Modifications**

Percent of active projects by Quarter
Number (N) of projects differs by Quarter

![Bar Chart]

Which Research Studies are included in Contract Mod metrics?

- Contract has been executed -AND-
- Study has started -AND-
- Study has not yet completed PCORI Peer Review

(This is a larger set of studies than assessed for On Track/Off Track, which focuses on the Research Period only)

Q2 data reflects pre-COVID impact; More on COVID impact will be shared in Q3 Dashboard
Section 3

PCORI Peer Review & Posting Results

We are working on developing quarterly targets.

Section Highlights

- There are 61 research projects in PCORI Peer Review or Translation
- 271 research projects have completed PCORI Peer Review & Translation
- In-depth focus in Q2
  NIH-001041

Speed of PCORI Peer Review

<table>
<thead>
<tr>
<th>Months</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>23</td>
<td>20</td>
<td>18</td>
<td>21</td>
</tr>
</tbody>
</table>

Median Time to Complete Peer Review (Grey = 75th Percentile)

Final Research Reports Posted to PCORI.org

<table>
<thead>
<tr>
<th>Months</th>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q4</th>
</tr>
</thead>
<tbody>
<tr>
<td>FRRs Posted</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

We are working on developing quarterly targets.
Studies in PCORI Peer Review Process or Completed PCORI Peer Review
N=347, as of Q2-20

15
In Process:
Research Period Complete; Drafting DFRR or undergoing Pre-Review Edits

6
In Process:
Undergoing PCORI Peer Review

30
In Process;
Final edits underway

25
PCORI Peer Review Complete;
Summaries being developed

271
Results Posted;
PCORI Peer-Reviewed results posted to PCORI.org

*Does not include Pilots, Evidence Synthesis, Rapid Cycle Research, Infrastructure, or D&I awards
Speed of PCORI Peer Review
Q2-20 Update

- **Target:** 6 months from acceptance of the Draft Final Research Report (DFRR) to acceptance of Final Research Report (FRR).

- **Time for PCORI Peer Review to-date:**
  - 295 completed as of Q2-20
    - Median time in Peer Review: 8.1 months (average 9.0 m)
    - Fastest to-date: 3.0 months; Slowest to-date: 25.5 months

---

**Dashboard Status: not Meeting Target**
- In Q2, Peer Review did not meet the target (median study complete in ≤ 6 months).
- See next slides for more information.
This figure groups studies by when their DFRRs were submitted, rather than by when they completed PCORI Peer Review (as shown on the main Dashboard).

In 4 years, we have cut the amount of time reports spend in peer review by half: 7 months from start to finish, though there is variation from quarter to quarter.

*We can calculate Q1-20 and Q2-20 median time when at least half have completed PCORI Peer Review.
Speed of Posting Results to PCORI.org
Q2-20 Update

- PCORI’s authorizing law requires that we make research findings available no longer than 90 days “after the conduct or receipt of research findings”
- This includes the time it takes to translate findings into lay and scientific text
- **All abstracts to-date have been posted within 90 days of completion of PCORI Peer Review**
- Time for Posting of Abstracts:
  - 271 completed as of Q2-20
    - Median time to post: 86 days (average 85 days)
The Final Research Report (FRR) is a comprehensive, full final report of the funded study, usually equivalent to the length and content of 3-5 journal articles. As of Q2-20, 150 FRRs have been posted to PCORI.org.

Dashboard Status: Target N/A
We are working on developing quarterly targets.
Attention to FRRs Posted to PCORI.org
Q2-20 Update

We are tracking downloads of the Final Research Reports (FRRs) posted on PCORI.org, including the top 10 most downloaded FRRs in each quarter.

**Most Downloaded FRRs in Q2-20**

<table>
<thead>
<tr>
<th>Title</th>
<th>Downloads</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comparative Risks and Benefits of Gender Reassignment Therapies</td>
<td>993</td>
</tr>
<tr>
<td>Comparative Effectiveness of Broad- versus Narrow-Spectrum Antibiotics for Acute Respiratory Tract Infections in Children</td>
<td>842</td>
</tr>
<tr>
<td>Reducing Health Disparities in Appalachians with Multiple Cardiovascular Disease Risk Factors</td>
<td>951</td>
</tr>
<tr>
<td>Shared Decision Making in the Emergency Department: The Chest Pain Choice Trial</td>
<td>207</td>
</tr>
<tr>
<td>Bringing I-PASS to the Bedside: A Communication Bundle to Improve Patient Safety and Experience</td>
<td>842</td>
</tr>
<tr>
<td>Preventing Venous Thromboembolism: Empowering Patients and Enabling Patient-Centered Care via Health Information Technology</td>
<td>993</td>
</tr>
<tr>
<td>Patient-Centered Support for Contraceptive Decision Making</td>
<td>207</td>
</tr>
<tr>
<td>Generating Critical Patient-Centered Information for Decision Making in Localized Prostate Cancer</td>
<td>993</td>
</tr>
<tr>
<td>Comparing Mobile Health and Clinic-Based Self-Management Interventions for Serious Mental Illness: Patient Engagement, Satisfaction, and Outcomes</td>
<td>842</td>
</tr>
<tr>
<td>Peer Health Navigation: Reducing Disparities in Health Outcomes for the Seriously Mentally Ill</td>
<td>951</td>
</tr>
</tbody>
</table>

**Downloads of Final Research Reports (FRRs), by Quarter**

- **Cumulative:** 2894 Downloads
- **Q3-19:** 207
- **Q4-19:** 842
- **Q1-20:** 951
- **Q2-20:** 993

NIH - 001047
PCORI-Funded Trials Publish Their Results as Quickly or Faster Than Studies Typically Do

% CER Results Published in Peer-Reviewed Journal Relative to PCD

- Field Benchmark
- PCORI Results Publications

Benchmark
Max: 60% at 60 mo.

Benchmarks Based on:

Cohort: PCORI's first 8 cycles (207 trials)
PCORI's Process Results in Complete and Earlier Availability of Results in the Public Domain

- **CER Results Publicly Available**: (Publication or Posted Abstract) Relative to PCD

  - **Field Benchmark**: Max: 60% at 60 mo.
  - **Public Availability of PCORI Results**: 100% at about ~30 mo.

**Benchmarks Based on:**

**Version:** 2/3/20
**Cohort:** PCORI's first 8 cycles (207 trials)
Public Availability of Primary CER Results

As of Q2-20, **237 studies have primary CER results peer-reviewed and publicly available**, and this number is steadily increasing

- **Primary results** are results that report on a comparison of clinical approaches using the pre-specified primary outcome(s). Also commonly referred to as primary publications, or Public Disclosure of Results (PDOR).

- Primary results can be **made publicly available** by being published in a peer-reviewed journal, and/or by completing the PCORI Peer Review Process and having abstracts posted to PCORI.org

Update:
As of 6/10/20, **249 Studies** have publicly available primary CER results
We are now monitoring attention to the project pages on PCORI.org that feature study results, by tracking total pageviews of results, as well as average pageviews of results (accounts for the increasing number of results available over time*)

Dashboard Status: Meeting Target
- We are exceeding the target of having an average of >100 pageviews per results page (target based on historical data)
- See next slide for the project pages that received the most attention this quarter

*This metric accounts for the increasing # of results available over time. (controlled by number of new results available in past year)
### Results Pages Drawing the Most Page Views Q2-20

In Q2-20 the 10 results pages drawing the most page views were:

<table>
<thead>
<tr>
<th>PCORI Page Title</th>
<th>Pageviews</th>
<th>Ave. Time on Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Comparing Broad- and Narrow-Spectrum Antibiotics for Children with Ear, Sinus, and Throat Infections</td>
<td>1,870</td>
<td>10:01</td>
</tr>
<tr>
<td>2 Examining Health Outcomes for People Who Are Transgender</td>
<td>1,162</td>
<td>11:15</td>
</tr>
<tr>
<td>3 Comparing Results of Three Treatments for Idiopathic Subglottic Stenosis</td>
<td>484</td>
<td>6:45</td>
</tr>
<tr>
<td>4 Identifying Personal Strengths to Help Patients Manage Chronic Illness</td>
<td>482</td>
<td>7:00</td>
</tr>
<tr>
<td>5 How Often Should Patients with Lung Cancer Have Imaging Tests after Surgery?</td>
<td>411</td>
<td>10:17</td>
</tr>
<tr>
<td>6 Evaluating Hormone Treatments for Women at Increased Risk for Preterm Birth – EPPPIC</td>
<td>380</td>
<td>5:15</td>
</tr>
<tr>
<td>7 The Benefits and Challenges of Using Multiple Sources of Information about Clinical Trials</td>
<td>344</td>
<td>5:17</td>
</tr>
<tr>
<td>8 Does Daily Self-Monitoring of Blood Sugar Levels Improve Blood Sugar Control and Quality of Life for Patients with Type 2 Diabetes Who Do Not Use Insulin? -- The Monitor Trial</td>
<td>238</td>
<td>7:29</td>
</tr>
<tr>
<td>9 Comparing Treatment for Ductal Carcinoma In Situ (DCIS) with or without Sentinel Lymph Node Biopsy</td>
<td>229</td>
<td>2:58</td>
</tr>
</tbody>
</table>
Section 4

Journal Articles Published

Section Highlights
- 97 journal articles published in Q2, including 22 CER Results
- 20 journal articles received high Altmetric (attention) scores
- In-depth focus in Q4
Journal Publications: Q2-20 Update

Out of the 97 articles resulting from PCORI-funded projects in Q2-20, 79 were empirical results, and 22 of those were CER results:

- **Articles Resulting from PCORI-funded Projects**
  - Q3: 188
  - Q4: 153
  - Q1: 141
  - Q2: 114

  - Total: 696

- **Key**
  - All Articles
  - All Empirical Results
  - CER Results

- **CER Results**
  - Q3: 41
  - Q4: 23
  - Q1: 23
  - Q2: 22

  - Total: 119

In addition to publications from PCORI-funded projects, we track journal publications that were by or about PCORI: There were 2 of these publications in Q2-20.

- **Articles By or About PCORI**
  - Q3: 7
  - Q4: 4
  - Q1: 0
  - Q2: 2

  - Total: 13

*Note: Current quarter counts are artificially low because some articles are not indexed right away.
Monitoring Attention to Journal Publications
CER Results from PCORI-Funded Studies

News and Blogs

News Articles Mentioning CER Results

Blogs Mentioning CER Results

Social Media (public posts only)

Tweets Mentioning CER Results

Facebook Posts Mentioning CER Results

NIH - 001055
What is an Altmetric Score?

A publication’s Altmetric score is a measure of Attention

- Altmetric is a tool that tracks a variety of sources to capture activity around publications (see list to left)
- Altmetric helps us track uptake into policy documents
- Altmetric data provides a unique record of how PCORI-funded research has been received and disseminated amongst different audiences around the world, and where it is having an influence on public policy

What’s a good Altmetric score?

In general, a high score is >20, which is attained by about 5% of all publications. A very high score is >100, attained by about 1% of all publications.

- Our highest scoring publication to-date has an Altmetric score of 1408 (self-monitoring of blood glucose results)
In the 2020 Dashboard, we are tracking the proportion of our CER Results publications in the top 10% of attention, controlling for journal and date of publication.

- Our target is for at least 10% of CER Results Publications to be in the top 10% of Altmetric scores (top 10th percentile).
- This has varied by quarter; For reference, in FY-2019, 14% of CER Results publications from PCORI funded studies were in the top 10th percentile.
- In Q2-20, 16% of CER Results from PCORI funded studies were in the top 10th percentile, above our target.

We are also tracking all publications from PCORI-funded studies to measure how many achieve scores ≥20, considered a high score by Altmetric.

- In Q2-20, there were 20 publications associated with PCORI-funded studies that achieved a score ≥20, and among those, 9 were CER Results.

Dashboard Status: Meeting Target

- We are meeting our target, which is for the attention given to our CER results publications to surpass the attention given to other publications in similar journals, published at the same time.
9 publications from Q2-20 have high Altmetric scores (≥20). Highlighted below are 4 Primary CER Results publications with high Altmetric scores. The score indicates attention in news articles (red), on social media (blues), and in blogs (gold).

<table>
<thead>
<tr>
<th>Altmetric</th>
<th>CER Results Publications Highlights</th>
<th>Score in Context</th>
</tr>
</thead>
<tbody>
<tr>
<td>189</td>
<td>Kluger BM, et al. Comparison of Integrated Outpatient Palliative Care With Standard Care in Patients With Parkinson Disease and Related Disorders: A Randomized Clinical Trial. <em>JAMA Neurology.</em> Feb 2020. [ Primary CER Results ]</td>
<td>Top 9% of attention, given the Journal</td>
</tr>
</tbody>
</table>
Section 5

Uptake of Results and Methodology Standards

Section Highlights

- In Q2, there were 5 citations of PCORI results in the UpToDate® decision tool.
- In Q2, we identified 21 citations in systematic reviews, guidelines, & policy documents.
- In-depth focus in Q4 NIH - 001059
We tracking uptake into the UpToDate® point-of-care decision tool. The target is to see increasing uptake of PCORI study results.

**Uptake into UpToDate®**

(Citations of PCORI CER Results on Topic Pages)

<table>
<thead>
<tr>
<th>Year</th>
<th>Q3-19</th>
<th>Q4-19</th>
<th>Q1-20</th>
<th>Q2-20</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>2017</td>
<td>5</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2018</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Dashboard Status: Meeting Target**

- The target is to see positive trends in uptake of CER results into UpToDate®

**Q2-20 Details: Topic Pages with Citations of PCORI CER Results:**

1. Behavioral and pharmacologic therapies for chronic insomnia in adults, update 1/7/20
2. Long-term care of the adult hematopoietic cell transplantation survivor, update 1/17/20
3. Treatment of urgency incontinence/overactive bladder in females, update 2/18/20
4. Patient evaluation and selection for antiviral therapy for chronic hepatitis C virus infection, update 2/19/20
5. Prostate cancer: Risk stratification and choice of initial treatment, update 3/26/20

**Cumulative: 46 Citations in UpToDate® Topic Pages**

NIH - 001060
For the 2020 Dashboard, we continue to track uptake into systematic reviews, meta-analyses, evidence-based clinical recommendations, and policy documents. The target is to see increasing uptake of PCORI study results.

**Dashboard Status: Meeting Target**
- The target is to see positive trends in uptake of study results systematic reviews, guidelines, and policy documents

*Note: Current quarter counts can be artificially low because some articles are not indexed right away*
Uptake of Methodology Standards  
Q2-20 Update

Citations of the PCORI Methodology Report*

Publications that Mention/Cite PCORI Methodology Standards

Unique Web Views

PCORI Methodology Landing Page

PCORI Methodology Report

PCORI Methodology Standards


*Note: Current quarter counts can be artificially low because some articles are not indexed right away.

Obtained via FOIA by Judicial Watch, Inc.
Section 6

Research in PCORnet

Section Highlights

- We are tracking PCORnet Front Door Request - there were 46 in Q2
- We now share the PCORnet Dashboard, created by the Coordinating Center
- We provide an in-depth focus in this Q2 Dashboard

Front Door Requests Submitted to PCORnet

- Q3
- Q4
- Q1
- Q2

Requests

0
10
20
30
40
50
**The Front Door is the access point** for potential investigators, patient groups, health systems, and sponsors to reach PCORnet resources and infrastructure. It is managed by the PCORnet Coordinating Center.

**Front Door Requests in PCORnet are being tracked**, which include Data Network Requests, proposal development, consultation, and general information.

An intake team educates requestors, advises on research designs, and connects opportunities with investigators across the Network.

**Dashboard Status: Meeting Target**

- We are meeting our target, which is to see consistent use of Front Door Requests, where collaborators access and/or leverage PCORnet infrastructure.
Many of the research studies using PCORnet are externally funded or co-funded. However, PCORI has not been able to track externally-funded studies for the past several reporting periods.

**Metric on Hold:**
- The infrastructure contracts with individual Clinical Research Networks (CRNs) have ended. During this time, PCORI was not collecting the progress reports where we learned about externally-funded studies.
- PCORI is in the process of reestablishing contracts with individual CRNs, and we will be able to collect data on externally-funded studies again in the future.
- In the meantime, we can look to the PCORnet Dashboard for some of this data. The PCORnet Dashboard shows that in 2019, there were 30 new studies funded that planned to use PCORnet infrastructure, including 25 studies not funded by PCORI.
Who Visits the Front Door?

- The Front Door team interacts with a variety of requestors.
- Requestors are frequently academic investigators, but also include funders representing federal, foundation, and industry partners.

Includes data based on requestor self-report and Front Door assessment from November 1, 2018 to January 31, 2020. Requests are attributed to the year they are received.
Why do they Visit the Front Door?

- Requestors often require consultation and support to understand how to leverage PCORnet resources to enhance their research.

- In some instances, the Front Door team supports proposal development, including how to properly budget for a project utilizing PCORnet partners and resources.

Includes data based on requestor self-report and Front Door assessment from November 1, 2018 to January 31, 2020. Network Collaborator Requests and Study Designation Requests were discontinued prior to November 1, 2018 with the initiation of PCORnet 2.0.

PCORnet uses Calendar Years, rather than Fiscal Years, therefore quarters don't line up with PCORI's fiscal quarters.
Improving data quality over time

- Foundational data curation is a **continuous learning cycle**
  - Continuous assessment of performance
  - Close gap between foundational and study-specific curation – add new data checks based on study findings

Percentage of Network with lab results and medication orders mapped to standard terminologies & encounter latency within threshold. Goal=100%
Over 260 Publications about PCORnet

- Publications and presentations about PCORnet infrastructure and research have increased over time.

- Recent high-impact articles have included the results from the PCORnet Bariatric Study. This manuscript is in the top 5% of all publications scored by Altmetric.


Includes data from PCORI, CC, and PCRF as of Q4 2019. N=299
Utilization of PCORnet resources

- Projects that leverage PCORnet resources do so in a number of ways.
- Most rely on the PCORnet Common Data Model (CDM), and an increasing number of times engage more than one Clinical Research Network (CRN).

<table>
<thead>
<tr>
<th>Year</th>
<th>CC</th>
<th>Single IRB</th>
<th>2+ CRNs</th>
<th>CDM</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>21%</td>
<td>7%</td>
<td>43%</td>
<td>100%</td>
</tr>
</tbody>
</table>
| 2016 | 5% |            | 16%     | 21%
| 2017 | 15%| 10%        | 25%     | 100%
| 2018 | 15%| 4%         | 27%     | 100%
| 2019 | 32%| 41%        | 56%     | 100%
| 2020 |    |            | 100%    | 100%

Includes funded projects only. N=114
Who is Funding Research in PCORnet?

- PCORI funds many research projects that rely on PCORnet infrastructure.

- Increasingly, other sponsors recognize the value of funding research that leverages PCORnet.

includes funded projects only through October 2019.
N=114

Figures do not yet reflect COVID-19 research, which will increase 2020 total to-date by at least $50M
Dimensions of data quality in PCORnet

- **Conformance** — Data adhere to the format of the CDM
  - Fields do not contain values outside of the CDM specification

- **Completeness** — Values appear where we expect them
  - Diagnosis codes have an associated diagnosis type (e.g., ICD-9, ICD-10, SNOMED)

- **Plausibility** — Values that appear make sense
  - Less than 5% of records are associated with a future date

- **Persistence** — Patients / records do not disappear between refreshes
  - Less than a 5% decrease in the number of patients or records in a CDM table between refreshes

Growth in foundational data quality checks over time.

Checks: Rules such as "Values must conform to CDM specifications"

Measures: The number of CDM tables and/or fields affected by the checks.
Assessing data availability through data curation

- Many EHR domains are being harmonized / standardized for the first time
- Standardization allows PCORnet to query all partners quickly and efficiently because the raw data have been converted to a common terminology

![Graph showing available laboratory results across the network and median number of unique LOINC codes within a DataMart](image)

Figure: Each bar indicates the number of available laboratory results across the network, in Billions. The line shows the median number of unique LOINC codes within a DataMart. We see an increase from a median of 16 LOINC codes in November 2016 to well over 1,000 codes in January 2020.
Improvements in data completeness

- PCORnet data curation process is used to monitor whether partners are populating key concepts of interest.
- The completeness of certain lab tests has seen marked improvement over time.

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum Creatinine</td>
<td>0%</td>
<td>25%</td>
<td>50%</td>
<td>75%</td>
<td>90%</td>
<td>100%</td>
<td>95%</td>
</tr>
<tr>
<td>White Blood Cells</td>
<td>0%</td>
<td>25%</td>
<td>50%</td>
<td>75%</td>
<td>90%</td>
<td>100%</td>
<td>90%</td>
</tr>
<tr>
<td>eGFR</td>
<td>0%</td>
<td>25%</td>
<td>50%</td>
<td>75%</td>
<td>90%</td>
<td>100%</td>
<td>90%</td>
</tr>
<tr>
<td>Hemoglobin A1c</td>
<td>0%</td>
<td>25%</td>
<td>50%</td>
<td>75%</td>
<td>90%</td>
<td>100%</td>
<td>90%</td>
</tr>
</tbody>
</table>

 Refresh Date (number of eligible DataMarts)
Understanding the availability of recent data

- Up-to-date data are critical if data from PCORnet are to serve as outcomes and endpoints in pragmatic clinical trials.
- A latency calculation was developed for ADAPTABLE and later incorporated into foundational data curation.

![EHR DataMarts with an encounter latency of ≤ 3 months](image)

**Eligible DataMarts**: PCORnet 2.0 DataMarts that include EHR data, inpatient, ambulatory, and/or Emergency Department encounters, do not use date obfuscation and were approved for the indicated refresh.
Section 7

Engagement and Communications

Section Highlights

- Communications metrics indicate strong performance
- We continue to have a high number of applicants for Engagement awards
- In-depth focus in Q4
Engagement Awards
Q2-20 Update (6 Most Recent Cycles)

Engagement Awards

- Letters of Intent Submitted
- Applications
- Awards

Engagement Awards Special PFA:
Community Convening and Accelerating the Adoption of Tools & Resources [Cycle 17]

Received 149 Letters of Intent and 25 applications as of Q2
Communications Metrics
Q2-20 Update

Social Media
New Twitter Followers by Quarter
Cumulative Twitter Followers: 17,846

E-mail
Email Open Rate
Email Click-Thru Rate

Website Traffic
Unique Web Visitors
Unique Web Visitors to Results Pages

Top Referring Institutions
Top Referring IP Addresses in Q2-2020
Staff and students at these institutions are navigating to the PCORI website

- National Institutes of Health
- Department of Veterans Affairs
- Duke University
- The Johns Hopkins Medical Institutions
- University of California San Francisco
- University of Washington
- University of North Carolina at Chapel Hill
- U.S. Dept. of Health and Human Services
- Massachusetts General Hospital
- Longwood Medical and Academic Area
- Emory University
- Kaiser Foundation Health Plan

Top Referring External Websites
Top Referring External Sites in Q2-2020
Not including referrals from Social Media, PCORnet, CVEN'T (annual meeting site)

- Rural Health Information Hub
- Wikipedia
- Pivot (funding site)
- Aspen University
- cfson.umd.edu
- Blackboard.com/Stony Brook
- PCORnet
- Institute for Healthcare Improvement
- National Association for Continence
- Psychiatric Nurses Association
- Prime Inc.
- HSRProj

NIH - 001079
Next quarter, Q3-2020, we will provide an in-depth look at progress of projects, recruitment, modifications, and the impact of COVID-19 on our portfolio.

The discussion is tentatively scheduled for the September 2020 Board Meeting.
Discussion Questions
The Q2 Dashboard will not be presented in depth during the June Board Meeting, but there will be opportunity for discussion

Questions for Discussion:

• Do our FY-2020 Dashboard and associated background materials cover the topics that are most important for the Board to review?

• Do you have concerns about our progress or performance on any of our Dashboard indicators?
PCORI Board of Governors Dashboard
Second Quarter FY-2020 (As of 3/31/2020)

Funds Committed

<table>
<thead>
<tr>
<th></th>
<th>Budgeted</th>
<th>Actual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>$155M</td>
<td>Q1</td>
</tr>
<tr>
<td>Q2</td>
<td>$84M</td>
<td>Q2</td>
</tr>
</tbody>
</table>

Operational Expenses

<table>
<thead>
<tr>
<th></th>
<th>Budgeted</th>
<th>Actual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>$155M</td>
<td>Q1</td>
</tr>
<tr>
<td>Q2</td>
<td>$84M</td>
<td>Q2</td>
</tr>
</tbody>
</table>

Research Project Performance

<table>
<thead>
<tr>
<th></th>
<th>Pre-COVID Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q3</td>
<td>Q4</td>
</tr>
<tr>
<td>Q1</td>
<td>Q2</td>
</tr>
</tbody>
</table>

Dashboard Key

- Q3 2019
- Q4 2019
- Q1 2020
- Q2 2020

Results Published in Literature

- CER Results
- Other Results

Altmetric: Attention to PCORI Results

- CER Results
- Other Results

Speed of PCORI Peer Review

- Median Time to Complete Peer Review (Grey = 75th Percentile)

Final Research Reports Posted to PCORI.org

- We are working on developing quarterly targets

Uptake into UpToDate®

- Cumulative: 46 Citations

Other Examples of Uptake

- Citations in Systematic Reviews, Guidelines, & Policy Documents

Results Viewed on PCORI.org

- Average Pageviews of Results Posted to PCORI.org

Front Door Requests to PCORnet

- Front Door Requests Submitted to PCORnet

Q2 data reflects pre-COVID impact; More on COVID impact will be shared in Q3-20 Dashboard
Francis,

Based on the recommendations from the DSMB that met late today, NHLBI is stopping the ORCHID clinical trial – this is the randomized controlled trial comparing hydroxychloroquine vs. placebo/Standard of care in hospitalized patients with confirmed SARS-CoV2 infection. This was a scheduled interim analysis – actually the 4th in a series – looking at both safety and outcomes data. **Bottom line:** There was no harm signal. However, based on the conditional power analysis there is less than a 1% probability that HCQ would prove more effective than standard of care even if we enrolled twice the number of patients. Therefore, we are concurring with the DSMB’s recommendation and stopping the trial in accordance with standard trial monitoring and oversight practices. The trial was almost completed (475 patients enrolled out of 510 target); however, based on these results there is no need to continue the study.

Notifications are underway to the investigative team, and the NHLBI communications office is already coordinating with OCPL, since we anticipate that there will be much public interest in this finding.

I will let Danielle know. Anyone else that I should ping?

Larry
Good evening,

For your awareness, please find attached and below a media availability from NHLBI on the DSMB decision to halt their hydroxychloroquine COVID-19 clinical trial. This will be sent to the department shortly. Please let me know if you have any questions or concerns.

Thank you,

Craig

Media advisory
Friday June 19, 2020

NIH halts clinical trial of hydroxychloroquine

Study shows treatment does no harm, but provides no benefit

What

A clinical trial to evaluate the safety and effectiveness of hydroxychloroquine for the treatment of adults hospitalized with coronavirus disease 2019 (COVID-19) has been stopped by the National Institutes of Health. A data and safety monitoring board (DSMB) met late today and determined that while there was no harm, the study drug was very unlikely to be beneficial to hospitalized patients with COVID-19. After its fourth interim analysis the DSMB, which regularly monitors the trial, recommended to the National Heart, Lung, and Blood Institute (NHLBI), part of NIH, to stop the study. NHLBI halted the trial immediately.

The Outcomes Related to COVID-19 treated with hydroxychloroquine among In-patients with symptomatic Disease study, or ORCHID Study, was being conducted by the Prevention and Early Treatment of Acute Lung Injury (PETAL) Clinical Trials Network of NHLBI. The data from this study indicate that this drug provided no additional benefit compared to placebo control for the treatment of COVID-19 in hospitalized patients.

The first participants enrolled in the trial in April at Vanderbilt University Medical Center, Nashville, Tennessee, one of dozens of centers in the PETAL Network. The blinded, placebo-controlled randomized clinical trial aimed to enroll more than 500 adults who are currently hospitalized with COVID-19 or in an emergency department with anticipated hospitalization. More than 470 were enrolled at the time of study’s closure.

All participants in the study received clinical care as indicated for their condition. Those randomized to the experimental intervention had also received hydroxychloroquine. Participants in the study will now continue to receive standard of care and follow up as indicated for their condition, but the administration of hydroxychloroquine has been stopped.

ORCHID participants had been randomly assigned to receive hydroxychloroquine 400 mg twice daily for two doses (day one), then 200 mg twice daily for the subsequent eight doses (days two to five) or a placebo twice daily for five days.
While COVID-19 usually presents as an acute respiratory infection, it can damage multiple organ systems, including heart, lung, and blood. Most adults with COVID-19 experience fever, cough, and fatigue and then recover within one to three weeks. However, some develop severe illness, typically manifesting as pneumonia and respiratory failure, with continued progression to acute respiratory distress syndrome and death.

Hydroxychloroquine is used to treat malaria and rheumatoid conditions such as arthritis. In various studies, the drug had demonstrated antiviral activity, an ability to modify the activity of the immune system, and it has an established safety profile at appropriate doses, leading to the hypothesis that it may have also been useful in the treatment of COVID-19.

Who
James P. Kiley, Ph.D., Director, Division of Lung Diseases, NHLBI.

Contact
To schedule press interviews, contact the NHLBI press office at nhlbi_news@nhlbi.nih.gov or at 301-496-5449.

------------------------------------------------------------------
Craig M. Fritz
Public Affairs Specialist
Office of the Director
Office of Communications and Public Liaison
National Institutes of Health
Building 1, Room 336
ph: (b) (6)
Media advisory
Friday June 19, 2020

NIH halts clinical trial of hydroxychloroquine
Study shows treatment does no harm, but provides no benefit

What
A clinical trial to evaluate the safety and effectiveness of hydroxychloroquine for the treatment of adults hospitalized with coronavirus disease 2019 (COVID-19) has been stopped by the National Institutes of Health. A data and safety monitoring board (DSMB) met late today and determined that while there was no harm, the study drug was very unlikely to be beneficial to hospitalized patients with COVID-19. After its fourth interim analysis the DSMB, which regularly monitors the trial, recommended to the National Heart, Lung, and Blood Institute (NHLBI), part of NIH, to stop the study. NHLBI halted the trial immediately.

The Outcomes Related to COVID-19 treated with hydroxychloroquine among In-patients with symptomatic Disease study, or ORCHID Study, was being conducted by the Prevention and Early Treatment of Acute Lung Injury (PETAL) Clinical Trials Network of NHLBI. The data from this study indicate that this drug provided no additional benefit compared to placebo control for the treatment of COVID-19 in hospitalized patients.

The first participants enrolled in the trial in April at Vanderbilt University Medical Center, Nashville, Tennessee, one of dozens of centers in the PETAL Network. The blinded, placebo-controlled randomized clinical trial aimed to enroll more than 500 adults who are currently hospitalized with COVID-19 or in an emergency department with anticipated hospitalization. More than 470 were enrolled at the time of study’s closure.

All participants in the study received clinical care as indicated for their condition. Those randomized to the experimental intervention had also received hydroxychloroquine. Participants in the study will now continue to receive standard of care and follow up as indicated for their condition, but the administration of hydroxychloroquine has been stopped.

ORCHID participants had been randomly assigned to receive hydroxychloroquine 400 mg twice daily for two doses (day one), then 200 mg twice daily for the subsequent eight doses (days two to five) or a placebo twice daily for five days.

While COVID-19 usually presents as an acute respiratory infection, it can damage multiple organ systems, including heart, lung, and blood. Most adults with COVID-19 experience fever, cough, and fatigue and then recover within one to three weeks. However, some develop severe illness, typically manifesting as pneumonia and respiratory failure, with continued progression to acute respiratory distress syndrome and death.

Hydroxychloroquine is used to treat malaria and rheumatoid conditions such as arthritis. In various studies, the drug had demonstrated antiviral activity, an ability to modify the activity of the immune
system, and it has an established safety profile at appropriate doses, leading to the hypothesis that it may have also been useful in the treatment of COVID-19.

**Who**
James P. Kiley, Ph.D., Director, Division of Lung Diseases, NHLBI.

**Contact**
To schedule press interviews, contact the NHLBI press office at nhlbi_news@nhlbi.nih.gov or at 301-496-5449.
FYI; also, NHLBI media avail will go out momentarily to say they are stopping their hydroxychloroquine study because of lack of efficacy.

Thanks,
Renate

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Good morning,

Best,
Kathy

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BULLETTIN—NIH Clinical Trial Evaluating Hydroxychloroquine and Azithromycin for COVID-19 Closes Early

June 20, 2020

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, has stopped enrollment in its clinical trial evaluating whether hydroxychloroquine and azithromycin can prevent hospitalization and death from coronavirus disease 2019 (COVID-19). This action was taken because NIAID, the study leadership and the independent data and safety monitoring board (DSMB) overseeing the trial determined that the rate of participant enrollment
has been inadequate for the trial to meet its objectives in a timely manner. No safety concerns were associated with the trial.

Launched in May 2020, the NIAID-sponsored Phase 2b trial aimed to determine whether a short course of hydroxychloroquine and azithromycin could safely and effectively prevent disease progression among adults with mild-to-moderate COVID-19. Hydroxychloroquine is approved by the Food and Drug Administration to treat autoimmune diseases and to prevent and treat malaria. Preliminary evidence had suggested that the drug, alone or in combination with the FDA-approved antibiotic azithromycin, might benefit people with COVID-19.

Although recent research suggests that hydroxychloroquine may not be an effective treatment for patients hospitalized with COVID-19, the question of whether it offers benefit when given early in the course of the disease remains unanswered. The NIAID study, conducted by the AIDS Clinical Trials Group (ACTG), sought to fill this knowledge gap by testing it in a randomized, placebo-controlled trial—considered the gold standard for determining whether an intervention can benefit patients.

The study, conducted at ACTG sites across the United States, planned to rapidly enroll approximately 2,000 adults who had laboratory-confirmed infection with SARS-CoV-2, the virus that causes COVID-19, and were experiencing symptoms consistent with COVID-19. Participants were randomly assigned to receive either hydroxychloroquine and azithromycin or matching placebo pills to take at home for seven days.

Since its launch in May, however, the study had enrolled only 20 participants, despite efforts by the study sites to enhance recruitment, raising concerns that it would not be feasible to continue the trial to full enrollment. On June 15, FDA revoked an Emergency Use Authorization that had allowed hydroxychloroquine and the related drug chloroquine to be prescribed to hospitalized adolescents and adults with COVID-19. This revocation does not apply to clinical trials and is specific to hospitalized individuals rather than outpatients. However, the decision could further dampen enthusiasm for enrollment in studies evaluating these drugs.

Based on these considerations and in close consultation with the study team, NIAID determined that it is highly unlikely that the ACTG trial, known as A5395, would be able to enroll to completion and meet its intended objectives. The DSMB concurred with this assessment and agreed it would be best to close the trial. Participants, site investigators, institutional review boards and regulators are being notified of this decision. The study team is working with the clinical trial sites to ensure that participants in the trial receive appropriate care.

NIAID remains committed to identifying safe and highly effective treatments for COVID-19. The Institute recently launched a trial evaluating remdesivir plus the anti-inflammatory drug baricitinib for treatment of hospitalized adults with COVID-19. Additional studies, including outpatient studies, are in the planning stages.

For more information about A5395, visit ClinicalTrials.gov and search identifier NCT04358068
Thanks, Not unexpected, but good o have solid science behind our recommendations. We now need results of the trials for prophylaxis.

Well, that fits with the outcome of the RECOVERY trial. I hope NHLBI will quickly publish the results.

Looping in Tony.

Francis

Based on the recommendations from the DSMB that met late today, NHLBI is stopping the ORCHID clinical trial – this is the randomized controlled trial comparing hydroxychloroquine vs. placebo/Standard of care in hospitalized patients with confirmed SARS-CoV2 infection. This was a scheduled interim analysis – actually the 4th in a series – looking at both safety and outcomes data. **Bottom line:** There was no harm signal. However, based on the conditional power analysis there is less than a 1% probability that HCQ would prove more effective than standard of care even if we enrolled twice the number of patients. Therefore, we are concurring with the DSMB’s recommendation and stopping the trial in accordance with standard trial monitoring and oversight practices. The trial was almost completed (475 patients enrolled out of 510 target); however, based on these results there is no need to continue the study.

Notifications are underway to the investigative team, and the NHLBI communications office is already coordinating with OCPL, since we anticipate that there will be much public interest in this finding.

I will let Danielle know. Anyone else that I should ping?

Larry
Thanks, Francis. You are correct.

Tony

Hi Tony,

I wanted to be sure you were aware that the letter to the EcoHealth PI went out yesterday. This reinstates the grant but immediately suspends it, pending responses to a number of important questions about WIV.

Francis
Many thanks, Mike

Attached is the incoming EcoHealth Alliance letter plus Mike’s draft of the response, with some edits and additions from me.

Please let me know how you would like to proceed.

Adrienne
Thanks so much Adrienne! I'll draft something today.

Mike

Sounds like a good plan.

FC
Good news! We are going to draft a response to the letter. Mike, can you help with the draft?

Thanks!

Adrienne
June 26, 2020

The Honorable Alex M. Azar II  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

Dear Secretary Azar,

We write with strong concerns surrounding the Administration’s termination of the National Institutes of Health (NIH) grant to EcoHealth Alliance on April 24, 2020.1 In the letter communicating the grant’s termination, NIH Deputy Director for Extramural Research, Dr. Michael Lauer, wrote that “At this time, NIH does not believe the current project outcomes align with the program goals and agency priorities.”2 However, press reports indicate that the grant was canceled because a small portion of the funding was to be given to the Wuhan Institute of Virology for on-the-ground sample collection and analysis.3 Given the potential for this study to inform our knowledge of coronavirus disease 2019 (COVID-19) transmission, it is deeply concerning that it may have been canceled for political reasons in the midst of the current pandemic.

It is always important that federal research priorities are driven by science-based decisions. This is especially true in a time that requires unparalleled investment in research that may help bring an end to this public health crisis. It is therefore troubling that this abrupt grant cancellation came just a week after President Trump announced that the Administration was looking into “grants going to that area” and continued that “we will end that grant very quickly.”4 This was in response to a reporter referencing false claims that COVID-19 “likely

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3 Id.
came from a Level 4 lab in Wuhan.”5 The Administration has been pushing this theory6 despite scientific experts saying this path of transmission would be virtually impossible given what is known about the virus and lab safety protocols.7 If this theory is the basis for the grant termination, it would be an egregious example of the Administration politicizing scientific decision making in order to further a politically convenient narrative.

EcoHealth Alliance’s grant was renewed in 2019 after an initial five-year grant on the same topic. The grant it received was extremely competitive – only 22 percent of proposals were funded in 2019.8 The July 2019 project proposal was titled, “Understanding the Risk of Bat Coronavirus Emergence.”9 In the midst of the COVID-19 pandemic that has taken over 115,000 American lives, it is inconceivable that this project would no longer “align with the program goals and agency priorities” of NIH. Any termination of a grant that has gone through NIH’s rigorous scientific review process must be adequately justified on a scientific basis – particularly a grant which would appear to be so relevant to understanding our current health crisis.

As the Committees of jurisdiction over public health and science, we need to better understand the decision to terminate EcoHealth Alliance’s NIH grant. We are especially concerned given Dr. Anthony Fauci’s, Director of NIH’s National Institute of Allergy and Infectious Diseases, assertion at a Committee on Energy and Commerce hearing on June 23 that “the grant was canceled because NIH was told to cancel it.”10 In order to understand how this decision was reached, we request a briefing to be delivered by July 15, 2020. At this briefing, we ask that you be prepared to address the following questions:

1. When the decision was made to terminate the grant to EcoHealth Alliance;

2. Who at HHS was involved in the decision to terminate the grant;

3. Whether entities outside HHS, including but not limited to the White House, the State Department, the National Security Council, and intelligence agencies, were involved in this decision;

5 Id.
4. The analysis conducted to determine that the EcoHealth Alliance grant’s project outcomes did not align with program goals and NIH priorities;

5. Any analysis conducted to determine EcoHealth Alliance’s alleged improper disbursal of NIH funds to the Wuhan Institute of Virology;

6. Any other decision NIH has made to terminate grants since January 1, 2020; and

7. Any further action NIH is considering taking regarding EcoHealth Alliance or any other grant holder regarding alleged relationships with international laboratories.

In addition to the briefing, we request the following materials be provided to the Committees no later than July 10, 2020. Please provide these materials in a searchable electronic format.

1. All documents and communications relating to the cancellation of EcoHealth Alliance’s grant, including the notification to and any response from EcoHealth Alliance;

2. All documents and communications regarding any potential direction from outside entities, including the White House or other Agencies or Departments, to terminate grants based on suspicion of collaboration with international laboratories;

3. All documentation of audits or other analyses conducted to determine improper disbursement of federal grant money from grant-holding institutions to other entities; and

4. The criteria that NIH used to assess the EcoHealth Alliance grant and determine that such grant merited cancelation, and documentation thereof.

Any decision to terminate a research grant should be conducted in a deliberative and transparent process that adheres to the highest standards of scientific integrity. Especially in this unprecedented time, it is important that our public health and science agencies remain free from political pressure and be allowed to pursue federally-funded research based on scientific merit.

Thank you for your attention to this matter. We look forward to speaking with you and reviewing the relevant materials.

Sincerely,

Eddie Bernice Johnson
Chairwoman
Committee on Science, Space, and Technology

Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce
Bill Foster  
Chairman  
Subcommittee on Investigations and Oversight  

Diana DeGette  
Chair  
Subcommittee on Oversight and Investigations
EcoHealth Alliance narrative
Mike Lauer (OER)
July 27, 2020
“Option 1c”
Hi Dr Collins

I hope you are fine, this is Sayeed, I am an inventor and scientist in the pharmaceutical product development field with primary focus on complex dosage forms like inhalation products (pMDIs, DPIs, Nebulizers). We are connected on LinkedIn - https://www.linkedin.com/in/sayeed-muhammad-mossadeq-26983a5/

I saw the news about the collaboration between NIH and public-private organizations to accelerate COVID19 treatments and therapeutics. In that perspective I wanted to contribute by sharing the novel inventions that I have perceived on the basis of drug repurposing - basically rerouting the already FDA approved anti-viral and anti-inflammatory compounds via the oral inhalation route instead of the oral tablet or intravenous dosage route. I am an individual scientist at the moment and I feel that by sharing my drug delivery concepts to the organizations in the collaboration the covid19 inhalation products can be accelerated so that the patients get the ultimate benefits.

Most of my recent inventions are for targeted delivery of anti-viral and anti-inflammatory compounds directly to the lung of the COVID-19 patients with an aim to simultaneously combat both the viral replication and cytokine storm - both of which are prevalent mainly in the lungs.

(b) (4)
So overall, my product concepts are based on not only delivering single anti-inflammatory or single anti-viral compounds to the lungs at any one time, but I propose a combination strategy where in 1 anti-inflammatory and 1 anti-viral compound OR multiple combinations of the compounds should be targeted directly to the lungs of the COVID-19 patients AND that the pressurized metered dose inhaler (pMDI) drug delivery strategy using HFA134a or HFA227 or a blend of both propellants might be the best choice as drug delivery strategies as they can offer a completely excipient free treatment, so that the unknown effects of any excipient on viral replication and inflammation can be bypassed. I have all the formulation and analytical parameters to make these combination products figured out overall and would be happy to collaborate with ACTIV participants and NIH scientists.

The availability of an inhaler could prove useful like a quick first aid kind of approach in a pandemic situation - especially when vaccines can take time - and especially when healthcare workers can quickly take a puff or multiple puffs from inhaler (without needing IV set up and circumventing tablet bioavailability issues) - and the rapid absorption from lungs can result in quick action in blood - like an army of anti-viral and anti-inflammatory compounds already dispatched on duty (prophylactic) to combat the virus if it gets into the healthy healthcare workers - this could prove useful in preventing or controlling significantly the spreading rate of the infection - because it takes 14 days to show symptoms if a healthy person gets infected. Therefore, a scenario where in a healthy person having taken a puff from inhaler (described here in this concept) and having unknowingly exposed to virus - compared to a scenario where the healthy person did not take any puff from an inhaler but still was unknowingly exposed would be the tie breaker that could highlight the importance of an inhaler (delivering both anti-viral and anti-inflammatory compounds) in tackling a viral pandemic.

I am currently trying to raise funds to develop these product concepts that I have and to generate the preclinical data, I would also be happy to collaborate with the ACTIV participants towards the goal, because as of now I am an individual scientist with no big affiliation but with good ideas, so collaborating with ACTIV participants should be a better way to transform these product concepts.

Thank you for your attention and please let me know if there is any thing else I can do to help.

Sincerely
Sayeed
Mobile (prefer to set up a time to talk) or Zoom call

NIH - 001186
PFA my email to FDA commissioner and reply from FDA covid19 team

On Sun, Jul 19, 2020 at 6:51 PM Sayeed M wrote:

Hi Dr Collins

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