Board of Governors Meeting
via Teleconference/Webinar

November 17, 2015

12:00-1:30 p.m. ET

pcori®

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Welcome and Introductions

Grayson Norquist, MD, MSPH
Chair, Board of Governors

Joe Selby, MD, MPH
Executive Director

Agenda

Time	Agenda Item
12:00 p.m.	Call to Order, Roll Call, and Welcome
12:00- 12:10 p.m.	**Consider for Approval:** Consent Agenda
12:10- 12:40 p.m.	Evaluation Update: Analysis of resubmissions
12:40- 1:00 p.m.	Annual Meeting Debrief
1:00- 1:15 p.m.	**Consider for Approval:** PCORnet Coordinating Center Funding Extension
1:15- 1:30 p.m.	Crowd-sourced CER Questions in Cardiovascular Disease: a PCORI Collaboration with the American Heart Association (AHA)
1:30 p.m.	Wrap up and Adjournment

Consent Agenda Items

Grayson Norquist, MD, MSPH

Chairperson, Board of Governors

Joe Selby, MD, MPH

Executive Director

Motion for Consent Agenda Items

- Approve minutes from September 28, 2015 Board meeting
- Approve nomination of Methodology Committee member Cindy Girman to serve on the Clinical Trials Advisory Panel (CTAP)
- Approve nominations by the Governance Committee for
  - Board Member Gail Hunt to leave the Research Transformation Committee (RTC) and be named to the Science Oversight Committee (SOC)
  - Methodology Committee Member Clyde Yancy to leave the Research Transformation Committee (RTC) and be replaced by Naomi Aronson, PhD
  - Methodology Committee Member Naomi Aronson to leave the Engagement, Dissemination, and Implementation Committee (EDIC) and be replaced by Mary Tinetti

We thank these members for their service, and look forward to their future contributions.

Cynthia Girman, DrPH

Naomi Aronson, PhD

Gail Hunt

Clyde Yancy, MD, MSc

Mary Tinetti, MD

Board Vote

Call for a Motion to:	• **Approve** each of the Motions on the Consent Agenda, as reflected
Call for the Motion to Be Seconded:	• **Second** the Motion • If further discussion, may propose an **Amendment** to the Motion or an **Alternative** Motion
Voice Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

Evaluation Update: Analysis of Resubmissions to PCORI

Laura Forsythe, PhD, MPH
Associate Program Director, Evaluation and Analysis

Lori Frank, PhD
Program Director, Evaluation and Analysis

Today's Presentation Goals

- Answer questions about resubmissions to PCORI:
  - How many applications are resubmitted?
  - What are the characteristics of applications that are resubmitted?
  - Are resubmissions more successful than first submissions? Why or why not?
- Discuss implications for PCORI
  - Facilitating revision process
    - Improving communication with applicants
    - Improving efficiency of resubmission process
    - Managing resubmissions fairly in light of changing program requirements

How many applications are resubmitted?

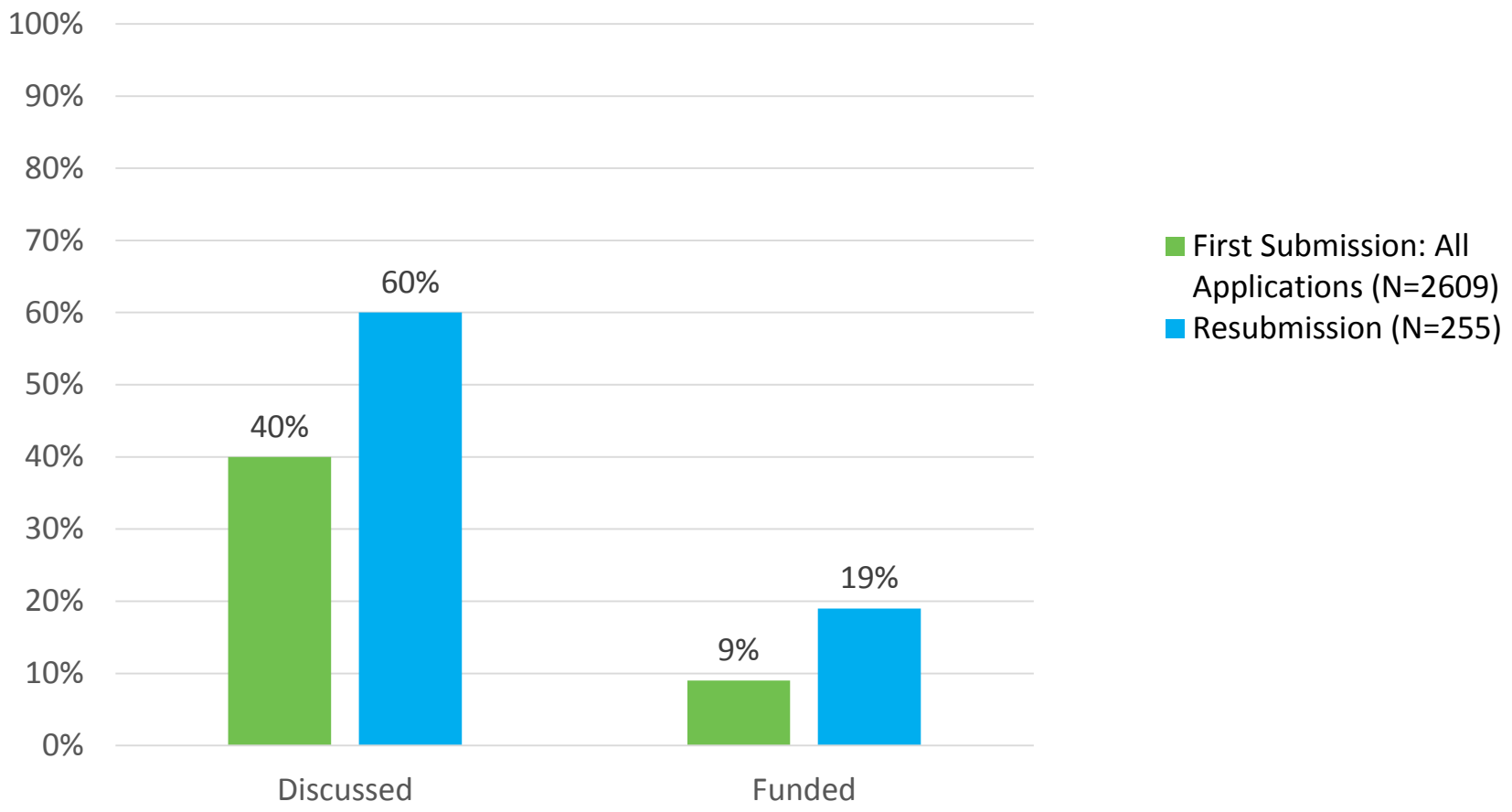
- Through 2014, PCORI received 2904 applications through the Broad PFAs
  - 10% of these were resubmissions
  - Most applications are resubmitted once (n = 261), but some are resubmitted twice (n = 27) or three times (n = 2)
- Up to 18% of unsuccessful applications from a given cycle are later resubmitted
- Most resubmissions are submitted two or three cycles later (65% and 24%, respectively)

What are the characteristics of applications that are resubmitted?

- Most applications that are resubmitted (86%) score in the top or middle tertile for online scores in the first submission
- A greater proportion of discussed applications are later resubmitted compared to those not discussed (20% vs. 6%)
- Most applications that are resubmitted (71%) score in the top or middle tertile for in-person scores in the first submission

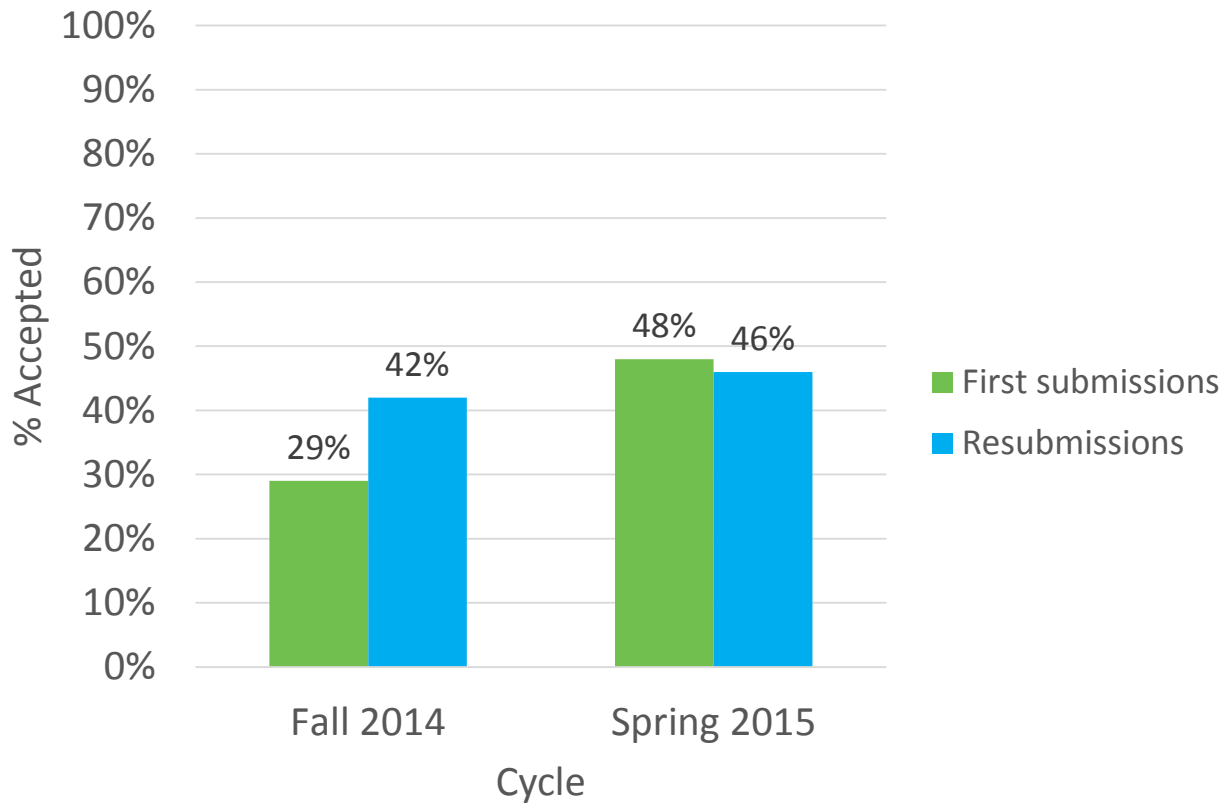
What Proportion of Resubmissions are Discussed and Funded?

Includes Cycle I through Fall 2014



A greater proportion of resubmissions are discussed and funded, compared to first submissions.

What Proportion of Resubmitted LOIs are Accepted?



Some applicants seeking to resubmit an application are not invited at the LOI stage.
More LOIs that were resubmissions, compared to first submissions, were accepted for Fall 2014.

How are resubmitted applications scored in PCORI Merit Review?

- Online overall scores improve by an average of 2.4 points for resubmissions
- In-person scores, on average, get worse by 3.8 points for resubmissions that are discussed (N = 113)
- Resubmissions we fund improve on:
  - nearly all criteria from all reviewer points of view
  - the online overall score (mean change = 6.4 points)
  - the in-person overall score (mean change = 14.5 points)

Next Steps

- Analysis of merit review critiques
  - To what extent are resubmissions responsive to reviewer comments? How does responsiveness relate to funding?
- Expand use of streamlined resubmission review

Summary

- How many applications are resubmitted?
  - Up to 18% of unsuccessful applications from a given cycle are resubmitted
- What are the characteristics of applications that are resubmitted?
  - Most resubmitted applications scored well initially
- Are resubmissions more successful than first submissions? Why or why not?
  - A greater proportion of resubmissions are funded than first submissions.
  - Resubmission success could be enhanced

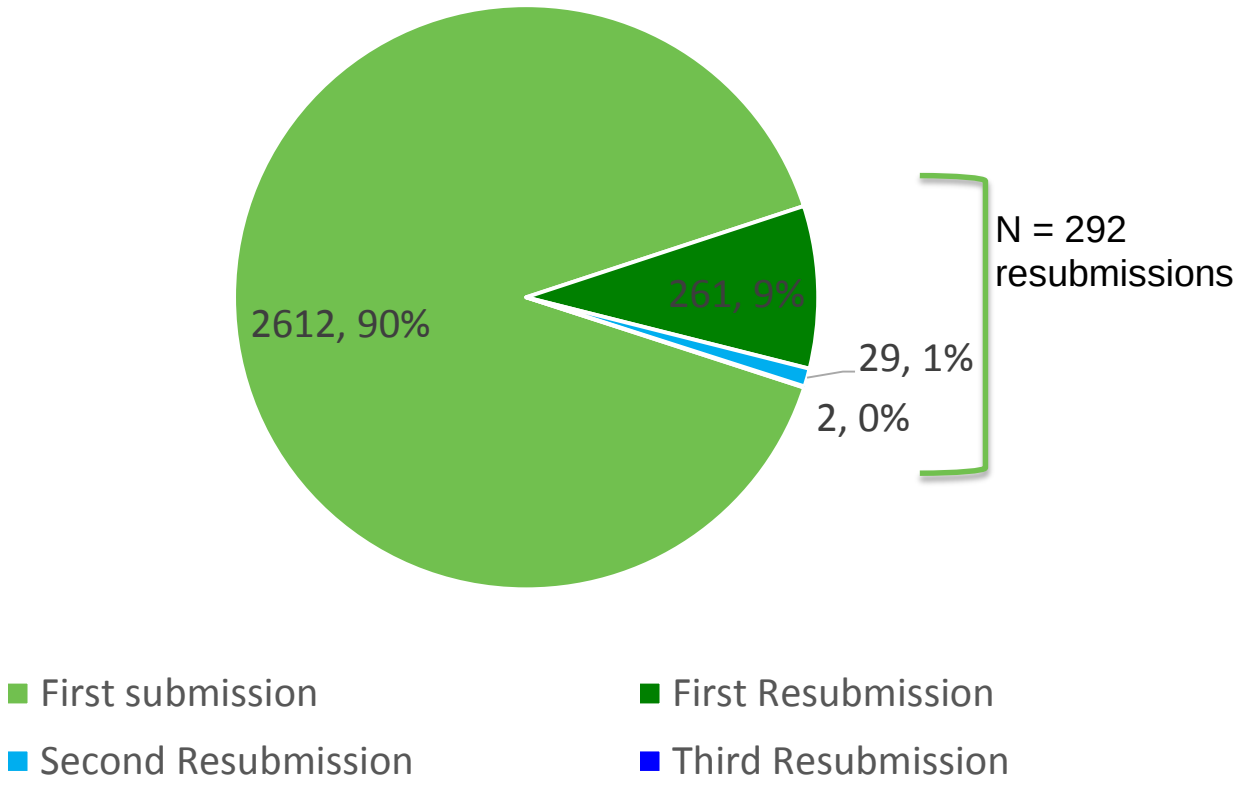
Discussion: Implications for PCORI

- Facilitating revision process
  - Improving communication with applicants
  - Improving efficiency of resubmission process
  - Managing resubmissions in light of changing program requirements

Appendix

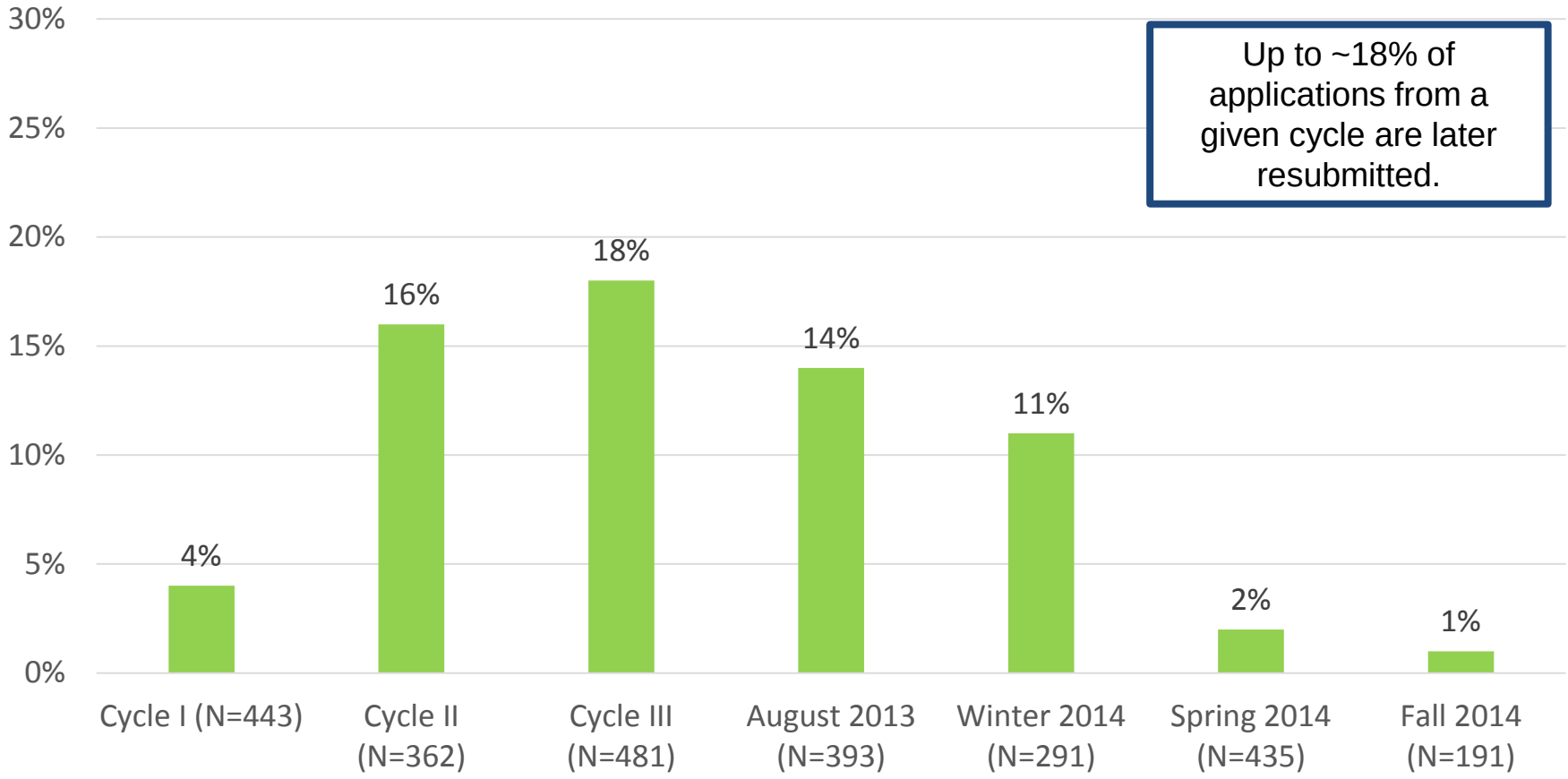
Resubmissions among all Applications (N = 2904)

Cycle I through Fall 2014



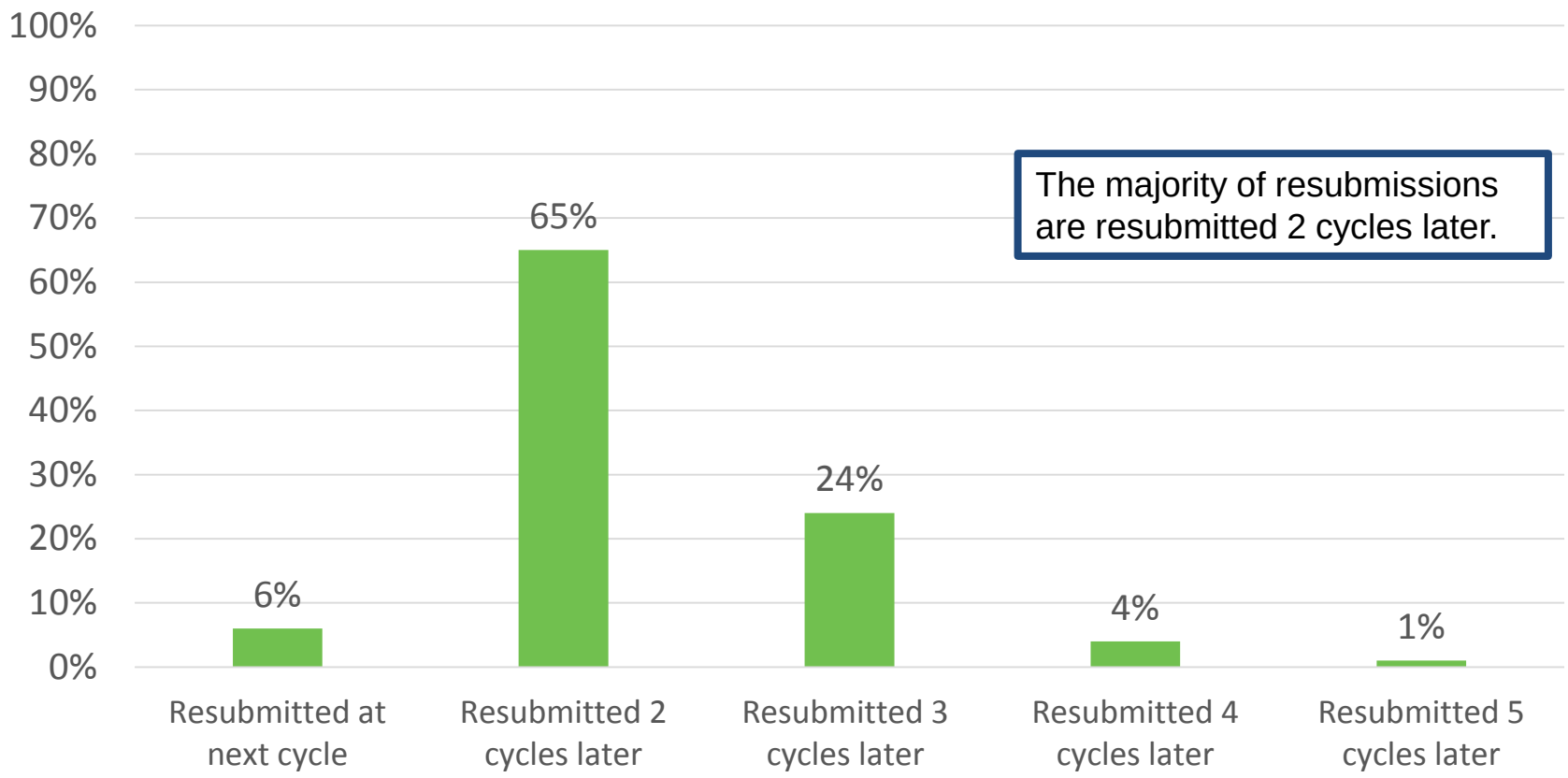
10% of all PCORI applications were a resubmission. Most applications are resubmitted one time.

Proportion of Applications Resubmitted

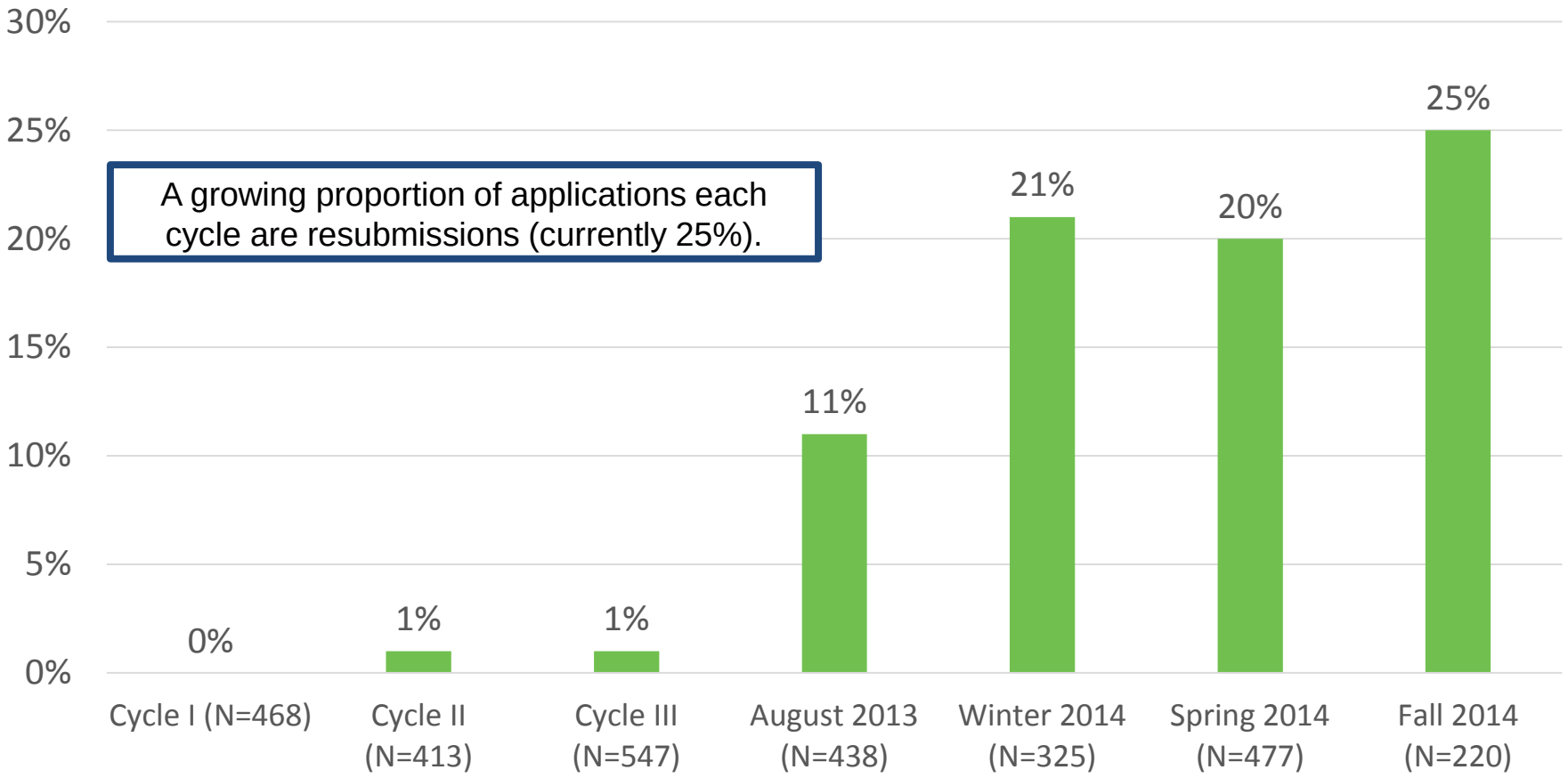


As additional review cycles take place in the future, the proportion of proposals that are resubmitted, particularly from Spring 2014 and Fall 2014, will likely increase.

Number of Review Cycles from First Submission to Resubmission (N=261)

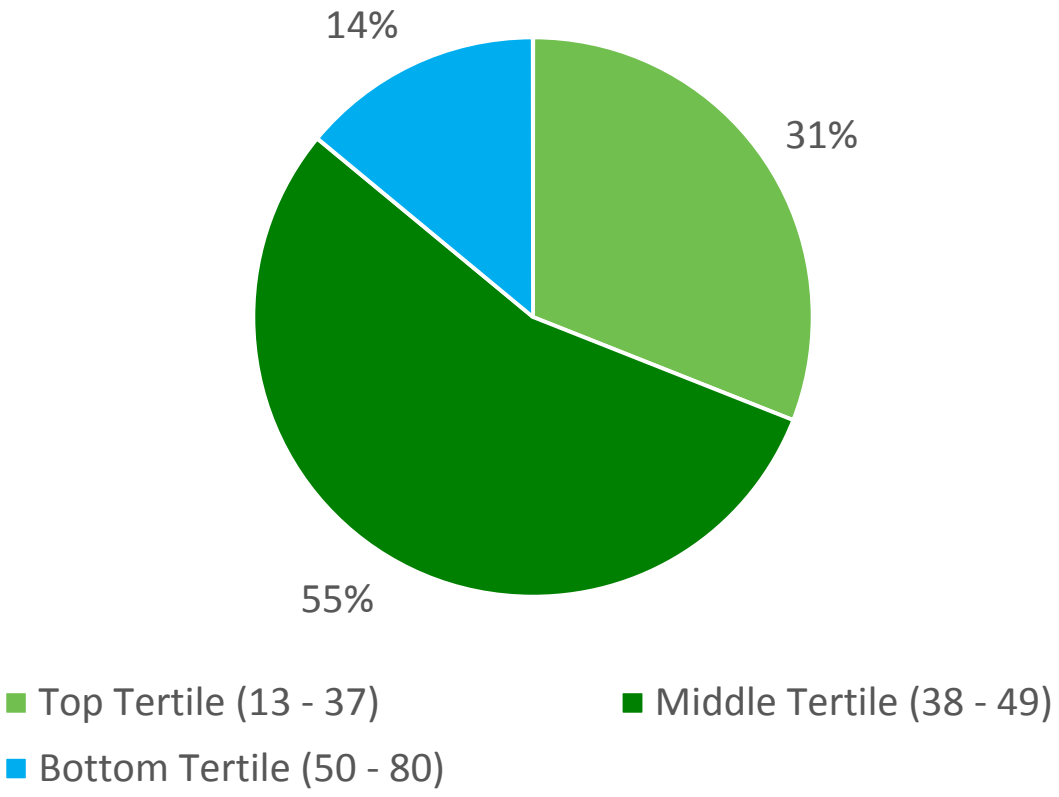


Proportion of Applications Received that are Resubmissions



Resubmissions by Online Scores for Original Submission (N = 250)

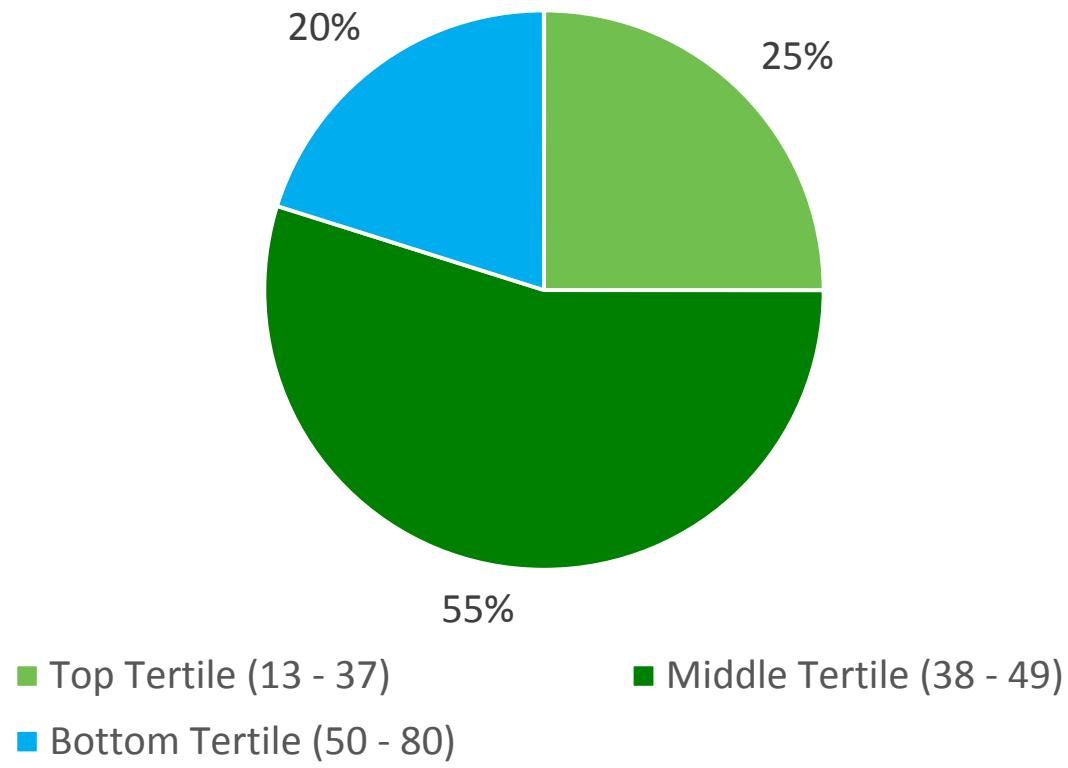
Cycle I through Fall 2014. Does not include 316 Cycle I proposals that did not progress to Phase 2



Most resubmissions scored in the top or middle tertile for the online overall score.

Resubmissions by In-Person Scores for Original Submission (N = 161)

Cycle I through Fall 2014. Does not include 316 Cycle I proposals that did not progress to Phase 2



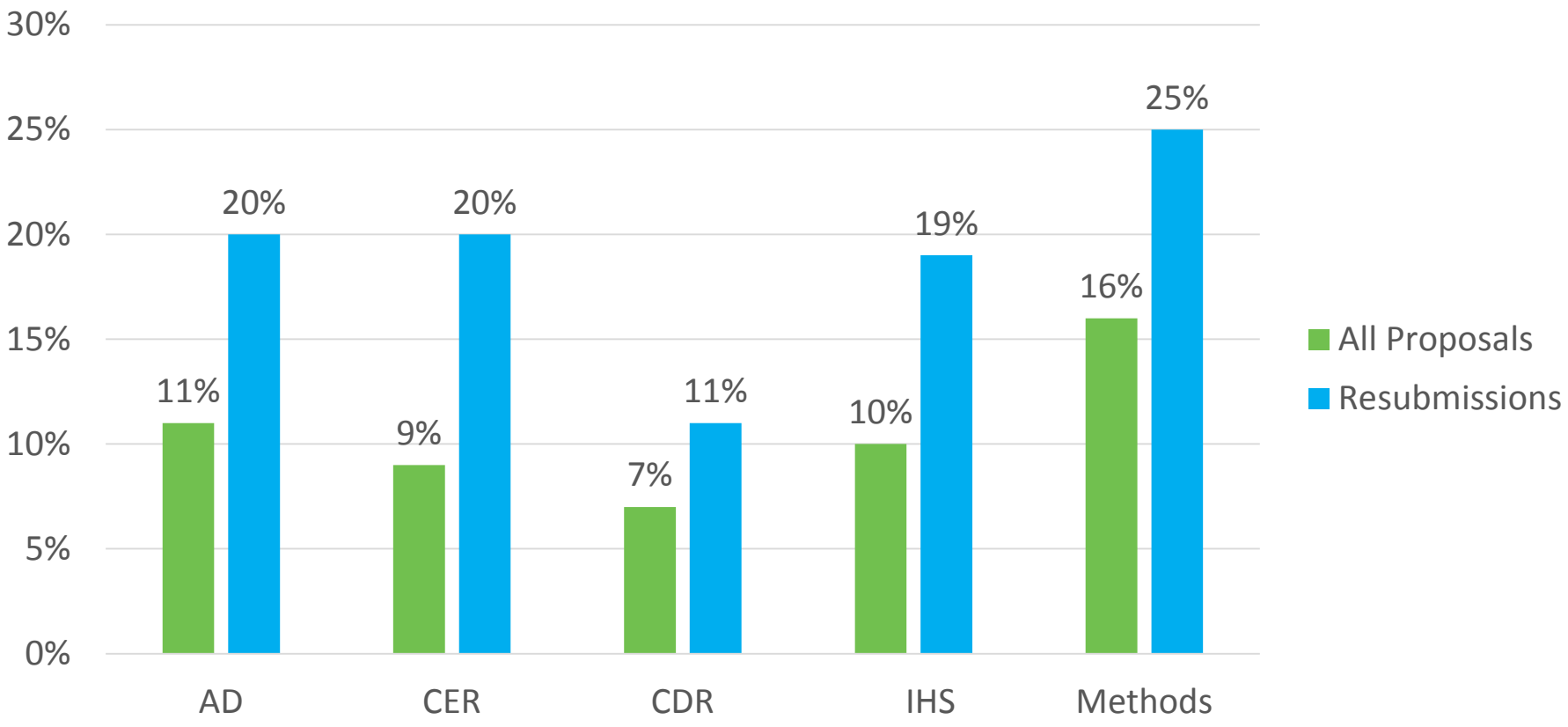
Most resubmissions that were discussed in the first submission scored in the top or middle tertile for the in-person overall score.

Flow of Applications– Key Points

- A greater proportion of discussed applications are later resubmitted compared to those not discussed (20% vs. 6%)
  - A greater proportion of resubmissions that were discussed in the first submission were funded, compared to those not discussed in the first submission (25% vs. 9%)
- Overall, a greater proportion of resubmissions are discussed and funded compared to first submissions (60% vs. 37% discussed, 19% vs. 10% funded)

Funding by Program and Submission History

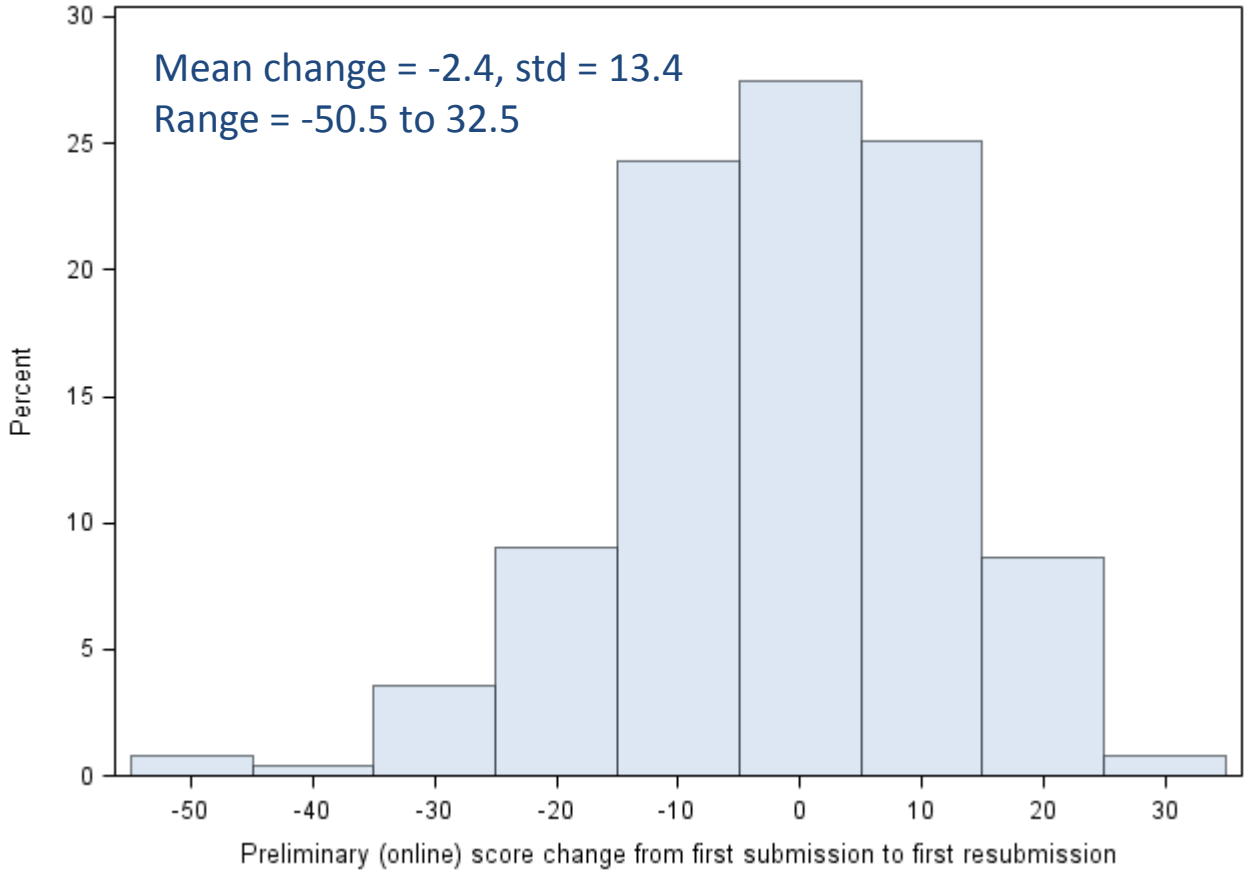
Cycle I through Fall 2014



PCORI programs fund between 7 and 16% of all applications and between 11 and 25% of resubmissions.

Change from First Submission to Resubmission: Online Overall Score (N=255)

Includes Cycle I through Fall 2014. Does not Include 316 Cycle I proposals that did not progress to Phase 2.



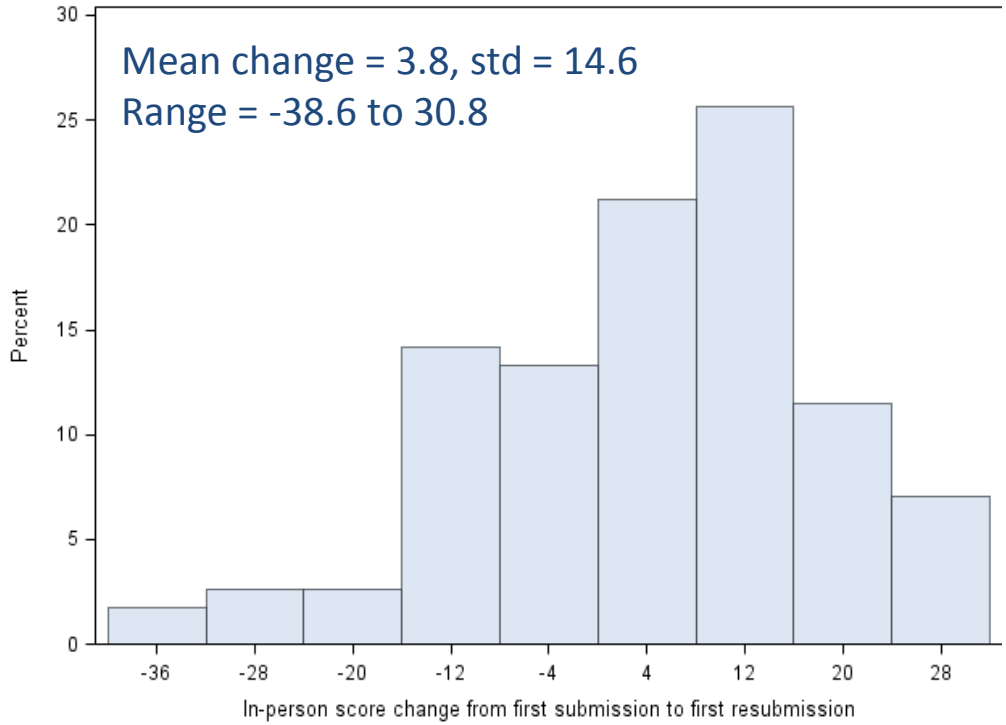
On average, mean online scores are slightly better (lower) for resubmissions

** Overall scores are on a scale of 10-90*

** A negative change indicates an improved score*

Change from First Submission to Resubmission: In-Person Overall Score (N=113)

Includes Cycle I through Fall 2014. Does not Include 316 Cycle I proposals that did not progress to Phase 2.



On average, mean in person scores are slightly poorer (higher) for the resubmission, although some application scores improve by more than 30 points.

** Overall scores are on a scale of 10-90*

** A negative change indicates an improved score*

Mean Scores for Review Criteria – Key Points

- Applications that are resubmitted tend to score better on the Review Criteria in both the first and second submission, compared to applications that are only submitted once

Change in Scores by Funding Status – Key Points

- On average, compared to resubmissions that are not funded, resubmissions that were funded had
  - Among scientist reviewers: larger improvements for Potential to Improve Healthcare, Technical Merit, and Patient-centeredness
  - Among both patient and stakeholder reviewers: larger improvements on Potential to Improve Healthcare, Patient-centeredness, and engagement
  - Larger improvements on the preliminary overall score and the final overall score

2015 PCORI Annual Meeting Debrief

Joe Selby, MD, MPH

Executive Director

Bill Silberg

Director, Communications

How'd we do?

- More than 1,300 attendees, including researchers (46%), patients and caregivers (26%), clinicians (10%), employers, insurers, others; 900+ registered for webcasts
- Four plenary sessions, including joint session on dissemination and implementation (with AHRQ)
- 30 breakout sessions organized by research priority, cross-cutting topics and major initiatives
- 100+ scholarships awarded to patients/caregivers and representatives of patient advocacy groups
- More than 6,800 posts on Twitter, with a reach of >19 million. Conversation was overwhelmingly positive

Attendee Survey

- 1,004 survey invitations sent
- 455 surveys received, 45% response rate
  - 51% researchers, 27% patients/caregivers/advocacy organizations, 22% other stakeholders
  - 50% have received PCORI funding, 41% have attended a PCORI event, 20% have served as a PCORI reviewer
  - Respondents heard about the meeting primarily through email invitations (62%), PCORI staff (32%), and/or research team members (28%)

Reasons for Attending

Top 5:

1. To network with others (69%)
2. To learn about PCORI's progress (60%)
3. To learn about the studies PCORI has funded (52%)
4. To learn more about patient-centered CER (51%)
5. To stimulate new ideas for my research (44%)

How Well We Met Those Objectives

	% Agree
The meeting generated valuable discussions	88%
I established new connections to researchers	68%
I established new connections to patients and/or other stakeholders	58%
The meeting helped me understand the work being funded by PCORI.	92%

How Well We Met Those Objectives

	% Agree
The meeting helped me understand the current state of the art for patient-centered CER.	81%
I learned about new research resources that will influence my future work.	66%
I learned about new methods for conducting research that will influence my future work.	60%
My participation in the meeting was worthwhile.	88%

Overall Meeting Experience

"I learned engagement strategies with participants and stakeholders that I am eager to apply to my currently funded PCORI project." [Researcher]

"I liked the diversity of attendees especially the ability for patients and key policy makers to be in the same room and treated equally. Everyone had their voice heard. It was impressive!" [Clinic/Hospital/Health System]

"I knew PCORI was important, but I felt a sense of community at the meeting that I hadn't felt before. I no longer think PCORI is trying to make CER happen, it has been successful. I saw the results." [Patient/Consumer]

Looking Toward 2016

- Tentatively scheduled for September 27-29, 2016 in the metro Washington, DC area.
- Multi-stakeholder steering committee to provide direction for themes and content.
- Consider new options for networking, facilitated researcher-patient “matchmaking,” more “practical” sessions
- Consider competitive call for presentations on non-PCORI funded PCOR/CER studies, including posters.
- Email annualmeeting@pcori.org with suggestions. All ideas welcome!

Questions/Thoughts?

PCORnet Coordinating Center Funding Extension

Contract Extension Approvals for:

1) Harvard Pilgrim Health Care (HPHC)

2) Genetic Alliance

Rachael Fleurence, PhD

Program Director, CER Methods & Infrastructure

Joe Selby, MD, MPH

Executive Director

Context

- In Phase I, the primary PCORnet Coordinating Center was contracted to Harvard Pilgrim Health Care (HPHC)
- In December 2014, funding was approved for a PPRN focused Coordinating Center to help advance the progress of the PPRNs
  - Contract was awarded to Genetic Alliance
- Given all current initiatives (including the Business Planning efforts) and vision-setting for Phase II, there is a need for additional time to fully establish the appropriate scope and budget for the Phase II Coordinating Center

Extension Justification

- Seeking supplemental funding through contract extensions to both the HPHC Coordinating Center and Genetic Alliance Phase I contracts
- Extend HPHC and Genetic Alliance contracts to align
  - HPHC: Modification to go from October 30, 2015 – February 29, 2016 (4 months)
  - Genetic Alliance: Modification to go from September 30, 2015 – February 29, 2016 (5 months)
- In October 2015, the RTC endorsed both requests for contract extensions and corresponding supplemental funding

Points of Clarification

- Phase II budgets will be reduced by the amount of these proposed extensions
  - Accountability regarding expected milestones and deliverables within the pre-determined timeline will still be ensured
- HPHC and Genetic Alliance scopes of work are continuations of ongoing work, with some capacities added during Phase I
- PCORI staff anticipates that Phase II contracts will be ready by the end of this extension period

HPHC: Proposed Scope of Work

- **Staffing and Operational Support**
  - Manage the PCORI contract and perform all associated tasks in coordination with PCORI and the Coordinating Center. Includes scientific and operational leadership functions, including strategic direction, program planning, and financial management
- **Workgroups**
  - Manage the workgroups that are currently in place in the following areas: IRB, Front Door, Contracting, Dashboard, and Industry
- **Communication/Web**
  - Support web strategy development and implementation as well as the central communication functions for PCORnet
- **Stakeholder Engagement**
  - Develop and host Best Practice Sharing Sessions and solicit engagement expertise
- **Data Coordination**
  - Manage the PCORnet data research network, including the common data model (CDM), data characterization, and liaise with partner networks to train and establish as functional networks

HPHC: Supplemental Budget Breakdown

Expense Category	Amount
Data	$1,376,781
Staffing and Operations Support	$438,739
Workgroups	$309,809
Front Door Implementation	$38,557
Communications/Web Support	$47,308
Stakeholder Engagement	$60,245
DRN Hosting	$92,000
Webinars/Recording	$10,000
Total	**$2,373,439**

HPHC: Supplemental Budget Request

Expense Category	Amount
Total Supplement Cost	$2,373,439
Unspent Funds on Original Contract	$384,000
Total Request	**$1,989,439**

Board Vote

Call for a Motion to:	• **Approve** $1,989,439 in total funds for HPHC through a contract extension through February 2016
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

Genetic Alliance: Proposed Scope of Work

- **Project Management**
  - Manage PCORI contract and perform all associated tasks in coordination with PCORI and the Coordinating Center
- **Network Operations**
  - Coordinate the development of a strong, trusted network, including establishing ways to efficiently share knowledge, leverage expertise, and build infrastructure throughout PCORnet
  - Build and manage the PCORnet Commons
- **Network Engagement**
  - Enable a pathway for rich and meaningful stakeholder and participant engagement
- **PPRN Coordination**
  - Maintain an efficient infrastructure, and knowledge and expertise sharing for the PPRNs

Genetic Alliance: Supplemental Budget Request

Expense Category	Amount
Personnel	$197,838
Operations and PPRN Coordination	$63,723
Network Operations	$173,968
Network Engagement	$88,436
Total Cost	**$523,965**

Board Vote

Call for a Motion to:	• **Approve** $523,965 in total funds for Genetic Alliance through a contract extension through February 2016
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

Crowdsourcing CER Questions in CVD: *A PCORI Collaboration with the American Heart Association*

Freda Lewis-Hall, MD
Chair, Research Transformation Committee

Joe Selby, MD
Executive Director

Goals & Deliverables

Create a transparent and public process for gathering meaningful CER topics from key stakeholders in cardiovascular disease

Deliverables:

1. Convening an expert AHA panel with PCORI representatives to identify key topic areas and an approach for soliciting CER questions
2. Access to AHA's extensive network, including 30,000 professional "solvers"
3. Engaging vendor for implementation
4. Considerable work capital and expertise from AHA in submissions review
5. Prioritization review process involving both AHA and PCORI representatives
6. Prizes of $10,000 each to the four best CER questions
7. Documentation and delivery of a detailed "blueprint" strategy for reproducibility in other disease areas at a marginal cost

Terms of the Collaboration

- The agreement gives PCORI significant input and direction in the collaboration
- No commitment at this time to further funding of the crowdsourced questions if we deem no submissions appropriate for the PCORI portfolio
- Prize-winning questions will be routed through PCORI's usual topic prioritization process, beginning with SOC review

Budget

- AHA provides funding and in-kind of $254,811
- PCORI provides funding of $411,493

AHA Announcement

- Nancy Brown, CEO of AHA, announced the collaboration at the Opening Plenary of AHA's Annual Scientific Sessions on November 8th

Project Timeline

- Nine month proposed timeline starting from the announcement with expected completion date August 2016

	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9
Announcement									
Challenge Design									
Challenge Promotion									
Challenge Implementation									
Evaluation									
Challenge Wrap-up									

Wrap Up and Adjournment

Grayson Norquist, MD, MSPH
Chair, Board of Directors