Board of Governors Meeting
via Teleconference/Webinar

February 24, 2015

12:00-2:00 p.m. ET

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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- 12:10 p.m.	Call to Order, Roll Call, and Welcome Consent Agenda: Consider for Approval • Minutes of Jan 27, 2015 Board Meeting • Committee Nominations and Changes as Recommended by the Governance Committee
12:10- 12:30 p.m.	Consider for Acceptance: FY2014 Audit Report
12:30- 1:00 p.m.	Consider for Approval: Slate of Spring 2014 Pragmatic Studies Awards
1:00- 1:45 p.m.	Consider for Adoption: Peer Review and Release of Research Findings Policy
1:45- 2:00 p.m.	Wrap up and Adjournment

Consent Agenda Items

Grayson Norquist, MD, MSPH
Chairperson, Board of Governors
Joe Selby, MD, MPH
Executive Director

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Motions for Consent Agenda Items

- Approve minutes from the January 27, 2015 Board meeting
- Approve the Committee nominations and Committee changes as recommended by the Governance Committee
  - Approve Committee Chairs, Vice Chairs, and Members as nominated by the Governance Committee
  - Approve transfer of responsibilities of the Audit and Conflict of Interest Subcommittee of the Governance Committee to the Governance Committee effective at the conclusion of the FY 2014 audit
  - Sunset the Audit and Conflict of Interest Subcommittee effective at the conclusion of the FY 2014 audit

Motion to Approve the Consent Agenda

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

FY 2014 Independent Auditor's Report

Larry Becker
Chair, Audit and COI Sub-Committee
Thomas J. Sneeringer, CPA
Partner, McGladrey
Regina Yan, MA
Chief Operating Officer, PCORI

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FY2014 Independent Auditor's Report

PCORI received an unmodified opinion; the financial statements presented fairly, in all material respects, the financial position, the results of operations, and its cash flows.

- There are no findings related to deficiencies in internal control over reporting.
- There are no findings related to compliance or other matters.

Statement of Activities

Statement of Activities	FY2014	FY2013
Revenue	$425,889,688	$240,837,570
Expenses	$161,862,176	$48,575,961
Change in Net Assets	$264,027,512	$192,261,609

FY2014 Financial Highlights

Cash at September 30, 2014	
	$626,434,736
Less Outstanding Obligations	
Liabilities	$43,621,986
Research Commitments	$554,177,534
Cash Available for Future Commitments	
	$28,635,216

Board Vote: FY 2014 Audit Report

Call for a Motion to:	• **Accept** the fiscal year 2014 Audit Report
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.

Spring 2014 Pragmatic Studies Slate

Christine Goertz, DC, PhD

Chair, Spring 2014 Pragmatic Studies Selection Committee

Bryan Luce, PhD, MBA

Chief Science Officer

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Cycle Overview and Slate Recommendation

Bryan Luce, PhD, MBA
Chief Science Officer

Spring 2014 Pragmatic Studies PFA

- Goal:
  - Fund pragmatic clinical trials (PCTs), large simple trials (LSTs), or large-scale observational studies that compare two or more alternatives for:
    - Addressing prevention, diagnosis, treatment, or management of a disease or symptom
    - Improving health care system-level approaches to managing care
    - Eliminating health or healthcare disparities
- Up to $10M in direct costs and up to 5 years duration
- Funds available up to $90M total costs

Spring 2014 Pragmatic Studies
Merit Review Criteria

1. Impact of the condition on the health of individuals and populations
2. Potential for the study to improve health care and outcomes
3. Technical merit
4. Patient-centeredness
5. Patient and stakeholder engagement

Slate Overview—Spring 2014 Pragmatic Studies
Process Overview

- 231 Letters of Intent (LOIs) submitted and reviewed
  - 40 invited to submit full application (17% of all LOIs)
  - 35 applications submitted (88% of invited) and reviewed at Merit Review
- Convened post-Merit Review methodology consultation panel with the assistance of our Methodology Committee and Clinical Trials Advisory Panel
- We are proposing to fund **5 applications** out of 35 (14%) **responsive applications**

Spring 2014 Pragmatic Studies PFA

Titles of Recommended Projects

Project Title
Enabling a Paradigm Shift: A Preference-Tolerant RCT of Personalized vs. Annual Screening for Breast Cancer[1, 2, 3]
Early Supported Discharge for Improving Functional Outcomes After Stroke [2]
A Pragmatic Trial to Improve Colony Stimulating Factor Use in Cancer[2]
Pragmatic trial of more vs. less intensive strategies for active surveillance of patients with small pulmonary nodules[1]
Targeted interventions to Prevent Chronic Low Back Pain in High Risk Patients: A Multi-Site Pragmatic RCT [1, 2]

- 3 applications align with PCORI priority topics, 4 align with IOM topics, and 1 aligns with AHRQ topics—priority areas are not mutually exclusive

1: PCORI Priority; 2: Institute of Medicine Top 100 CER Topic; 3: AHRQ Future Research Needs Topic

Project #1
Enabling a Paradigm Shift: A Preference-Tolerant RCT of Personalized vs. Annual Screening for Breast Cancer

- Research Question
  - Does personalized breast cancer screening (based on estimated risk and patient preferences) provide more effective cancer detection than annual screening?
- Study Design/Sample Size/Priority Population
  - RCT (N = 65,000) with observational cohort
  - Women (40 to 80 years old)
- Outcomes
  - Incidence of breast cancer stage IIB or higher
  - Number of procedures and detection of ductal carcinoma in situ (DCIS)
- Total Budget: $14M

Project #1 (cont.)
Enabling a Paradigm Shift: A Preference-Tolerant RCT of Personalized vs. Annual Screening for Breast Cancer

- Engagement
  - Interactions with American Cancer Society, Cancer CAREpoint, Community Mammography Assess Project, Zero Breast Cancer, FORCE, LIVESTRONG Foundation, The National Breast Cancer Coalition, and Susan G. Komen
  - External Advisory Board includes representation by relevant national payers, purchasers, government, and policy makers
- Potential Impact
  - Provides evidence on a potentially more patient-centered approach to breast cancer screening

Project #2
Early Supported Discharge for Improving Functional Outcomes After Stroke

- Research Question
  - What is the comparative effectiveness of using an advanced practice multidisciplinary discharge planning and in-home treatment team versus usual care in improving outcomes for stroke survivors discharged to the home?
- Study Design/Sample Size/Priority Population:
  - Cluster RCT; targeting 6,000 stroke patients discharged to home from 50 hospitals
- Outcomes
  - Primary: stroke survivor functional status at 90 days post discharge
  - Secondary outcomes include caregiver strain, all-cause readmissions, patient care experience, mortality (one year)
- Total Budget: $14M

Project #2 (cont.)
Early Supported Discharge for Improving Functional Outcomes After Stroke

- Engagement
  - American Stroke Association, American Hospital Association, State-based Stroke Collaborative, and State-based Center for Health Disparities
- Potential Impact
  - Reduce the incidence of functional impairment and stroke mortality
  - Reduced unnecessary stroke patient readmission rates
  - Reduce caregiver burden

Project #3
Standing Order Entries to Improve Primary Prophylactic Use of Colony Stimulating Factors (CSF)

- Research Question
  - Do standing order entry systems versus usual care improve the management and patient outcomes of cancer patients at risk for febrile neutropenia (fever with low white blood cells)?
- Study Design/Sample Size/Priority Population
  - Cluster RCT, 32 practices; 5,136 colon, lung, and breast cancer patients receiving supportive colony stimulating factors (CSF)
- Outcomes
  - Febrile neutropenia, health-related quality of life, adherence to standing orders, ER use/hospitalizations
- Total Budget: $8M

Project #3 (cont.)
Standing Order Entries to Improve Primary Prophylactic Use of Colony Stimulating Factors (CSF)

- Engagement
  - American Cancer Society, American Society of Clinical Oncology, America's Health Insurance Plans, and the National Comprehensive Cancer Network
- Potential Impact
  - Reduce clinical and financial harm to cancer patients who now experience overuse and underuse of CSF
  - Improvement in clinical and functional outcomes of patients at intermediate risk of febrile neutropenia

Project #4
Pragmatic Trial of More vs. Less Intensive Strategies for Active Surveillance of Patients with Small Pulmonary Nodules

- Research Question
  - What is the comparative effectiveness of more intensive vs. less intensive radiological surveillance of patients with small pulmonary nodules found during CT screening exams?
- Study Design/Sample Size/Priority Population
  - Cluster randomized trial (N = 46,810); adults >65, racial and/or ethnic minorities
- Outcomes
  - Tumor stage, timeliness of lung cancer treatment, lung cancer survival, emotional distress, anxiety, health status, satisfaction, adherence, resource utilization
- Total Budget: $14M

Project #4 (cont.)
Pragmatic Trial of More vs Less Intensive Strategies for Active Surveillance of Patients with Small Pulmonary Nodules

- Engagement
  - American Cancer Society, American Lung Association, Center for Medical Consumers, and Free to Breathe
- Potential Impact
  - Will reduce high clinical uncertainty about surveillance schedules

Project #5
Targeted Interventions to Prevent Chronic Low Back Pain (LBP) in High Risk Patients: A Multi-site Pragmatic RCT

- Research Question
  - Is prompt referral to evidence-based physical therapy (PT), augmented with cognitive behavioral principles vs standard therapy with a primary care physicians, for high risk patients presenting with acute LBP more effective in preventing the progression to chronic LBP?
- Study Design/Sample Size/Priority Population
  - Multi-site cluster pragmatic RTC; N = 2,600+; 60 clinical sites across 5 regional areas
  - African-American and Hispanic/Latino groups; rural and urban areas; low-income groups
- Outcomes
  - Rate of transition to chronic LBP; disability index and functional impacts on patients (e.g., daily living and social life, etc.); healthcare utilization
- Total Budget: $14M

Project #5 (cont.)
Targeted Interventions to Prevent Chronic Low Back Pain (LBP) in High Risk Patients: A Multi-site Pragmatic RCT

- Engagement
  - Care delivery systems (including primary care practices) and the patient/clinician groups, payers, electronic medical record (EMR) system vendors, and national primary care and physical therapy professional societies; American Chronic Pain Association
- Potential Impacts
  - Potential changes in clinical practices for low back pain

Slate Budget Overview–
Spring 2014 Pragmatic Studies PFA

5
New Projects

PFA	Allotted	Proposed Total Budget*	*Difference*	Average Project Budget*
Pragmatic Clinical Studies and Large Simple Trials to Evaluate Patient-Centered Outcomes	$90 Million	$64,140,036	*-$25,859,964*	$12,828,007

NOTE: Staff will negotiate (as necessary) contract terms to strengthen study design or adherence to Methodology standards before contract execution. All awards are contingent on meeting contract terms as specified by PCORI.

*Total budget = direct + indirect costs

VOTE: Approve Funding for Recommended Slate from Spring 2014 Pragmatic Studies PFA

Call for a Motion to:	• **Approve** funding for the recommended slate of awards from the Spring 2014 Pragmatic Studies PFA
Call for the Motion to Be Seconded:	• **Second** the Motion • Move to **discuss, amend, or take another action** on the selected topic
Roll Call Vote:	• Vote to **Approve** the **Final** Motion • Ask for votes in favor, opposed, and abstentions

PCORI's Proposed Process for Peer Review of Primary Research and Public Release of Research Findings

Revisions and response to public comments

Joe Selby, MD, MPH
Executive Director
Bill Silberg
Director, Communications

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Agenda

- PCORI's obligations under the authorizing legislation
- Public comment: process and general themes identified
- Proposed revisions to the process
- Revised process and timeline
- Discussion and vote to adopt the proposed process

Acknowledgements

Thanks to those who have done the hard work you're seeing today:

- Harold Sox
- Joe Selby
- Mary Hennessey
- Jean Slutsky
- Thomas Workman, Marla Clayman, and AIR staff
- Marla Bolotsky and web team
- Richard Schmitz and Golin
- Blake Whitney
- Francis Collins and the National Institutes of Health staff
- Engagement, Dissemination, and Implementation Committee (EDIC)
- Bill Silberg
- Orlando Gonzales

PCORI's Obligation Under its Authorizing Legislation

Conduct Peer Review of Primary Research

- Assess scientific integrity
- Assess adherence to PCORI's Methodology Standards

Release of Research Findings

- No later than 90 days after "conduct or receipt"
- Make available to clinicians, patients, and general public
- Make comprehensible and useful to patients and providers for healthcare decisions
- Include considerations specific to certain sub-populations, risk factors, and comorbidities
- Describe process and methods, including conflicts of interest
- Include limitations and further research needed

Public Comment Process Timeline

Status	Time	Item
✓	Sept 15	PCORI Board voted to accept the draft proposal for public comment and release of research findings
✓	Sept 15 to Nov 7	Public comment period
✓	Sept 29	Live public forum: Multi-stakeholder panel
✓	Oct 29	Webinar: Multi-stakeholder panel
✓	Nov 18	PCORI Board presented with update on the public comments (quantitative)
✓	Dec 15	Stakeholder Advisory Council reviewed and confirmed the themes and major revision recommendations
✓	Jan 20	EDIC meeting discussed public comments/themes and approved proposed approaches to revisions
	Feb 24	PCORI Board vote on the revised process for peer review and release of research findings

Thematic Analysis: Conducted by American Institutes of Research (AIR)

- Coding of comments
  - Relevance
    - To specific section or overall process
  - Level of Agreement
    - Agree, Agree with Caution, or Disagree
  - Affect
    - Positive, Negative, or Indifferent
  - Suggested Action/Direction of Revision
    - Add Something, Remove Something, or Modify Something

Thematic Analysis: Conducted by AIR

Identified themes based on four criteria:

- The prominence of the theme across comment submissions
- The clarity of the comment toward providing a recommendation for revision
- Tensions between stakeholder perspectives
- The “weight” of the comment’s source
    - A comment is given additional weight when it represents the collective voice of a larger constituency, such as an organization or society.

Public Comment: Nine Recommendations for Revision

- **Incorporate patients and other stakeholders** into the process of peer review, preparing materials for public release, and broader dissemination plans.
- Establish a clear process for **resolving potential disagreements** or differences in interpretation between changes to a final report resulting from PCORI peer review and those required by a journal review.
- Create a **standardized approach to the selection of peer reviewers** and the peer-review process as a whole.
    - Add details into the process about how PCORI will select the peer reviewers or use a vendor to provide peer review of the reports.
    - Include in the process a clear set of standards regarding who is appropriate to provide scientific peer review and the basis of the scientific review.

Public Comment: Nine Recommendations for Revision

- Clarify or revise the process to indicate the relationship between this **process and PCORI's broader plan and efforts to disseminate research findings.**
- Clarify **the purpose and approach to the methodological review** of the report.
- **Reduce the required reading level** of the lay abstract to below 8th grade.
- Clarify within the process how researchers can be **assured that the publication of an abstract and table** in ClinicalTrials.gov and the lay abstract on the PCORI website **will not** be viewed as **potentially jeopardizing publication in academic journals.**

Public Comment: Nine Recommendations for Revision

- Make the entire **review process transparent** so that reviewer comments and researcher responses are available to the public.
- Add the requirement of a formal **evaluation of the process in one year.**

Revisions: Includes Public Comments, and Input from PCORI Methodology Committee and NIH

1. Incorporate patients and other stakeholders	2. Process for resolution of disagreements or differences	3a. Selection of peer reviewers	3b. Standards for who is appropriate to provide peer review
4. Relevance to the broader D&I plan	5. Purpose and approach to methodological review	6. Reduce required reading level	7. Assure the abstract and tables are not prior publication
8. Evaluate process after one year	9. Make the process transparent	10. Harmonization with NIH/FDAAA	11. Minimize burden to Awardees

Public Comments NIH and MC Public Comments, NIH, and MC

What We Heard	PCORI's Response	Draft Revision Language
1. **Incorporate patients and other stakeholders into the peer review, lay abstract, and dissemination processes.**	PCORI is committed to including patients and other stakeholders at every stage of the research and dissemination processes. We have modified the document accordingly.	**Reviewers for a particular draft final report will include** the Methodologist and/or biostatistician, External subject matter experts, **Patient/caregiver and other stakeholder reviewers: At least one patient and/or caregiver with experience with the disease or condition relevant to the study will be invited to serve as a reviewer, commenting on the study's relevance and usefulness. The goal will be to determine if patient/caregiver perspectives, values and preferences were adequately considered in the report's summary of the study's results and to confirm that the results are useful to them in making decisions about care options. As appropriate, a representative of another stakeholder group, such as payers, employers, the life sciences industry, or policy makers, also may be invited to comment as part of the review process.** Creating and posting the 500-word (lay) abstract for patients, consumers, and the general public addresses… a. PCORI will select a qualified and experienced contractor to develop all of the lay abstracts in a manner and format that is consistent. b. The **contractor will be required to conduct cognitive and focus testing, ensure that the abstracts are appropriate reading level, and include patients to ensure that the findings are comprehensible.**

What We Heard	PCORI's Response	Specific Language Changes to Draft process
2. Establish a clear process for the resolution of potential disagreements or differences in interpretation between required changes to a final report by the PCORI peer review and those required by a journal review.	PCORI recognizes that the conclusions in the peer-reviewed final report may differ from what appears in journal publications, for a variety of reasons. PCORI will work closely with investigators to update material posted on pcori.org to note any updates in findings based on publications. To the fullest extent possible, PCORI's process will be coordinated with a journal's review process.	**There may be times when there is a material difference of opinion between the Awardee's Principal Investigator and PCORI about reviewer comments or proposed revisions …**
9. Make the entire review process transparent so that reviewer comments and researcher responses are available to the public.	PCORI agrees that for purposes of transparency, anonymized reviewer comments, and awardees' responses, will be posted as part of PCORI's review process.	**… the final report as revised by agreement between PCORI and the Awardee will be posted on PCORI.org, along with the anonymized comments of the peer reviewers and the Awardee's response.**

What We Heard	PCORI's Response	Specific Language Changes to Draft process
3. a and b. Create a standardized approach to the selection of peer reviewers and the peer-review process as a whole. Include details in the process about how PCORI will select the peer reviewers or use a vendor to provide peer review of the reports.	PCORI's agrees that more detail about the review process is useful and warranted.	PCORI shall engage a **qualified contractor**, who will be closely managed by PCORI staff, to administer the peer review of draft final reports. Reviewers for a particular draft final report will include the **Methodologist and/or biostatistician, External subject matter experts, Patient/caregiver and other stakeholder reviewers.** The **Principal Investigator shall recommend up to two subject matter experts** for PCORI to consider inviting to participate in the review of the final report. Clinical, scientific, and technical experts from drug and device manufacturers may be among those chosen as methodologists or content experts.
4. Clarify or revise the process to indicate the relationship between this process and PCORI's broader plan and efforts to disseminate research findings.	PCORI agrees that it would be helpful to clarify how the peer review and public release process fits within PCORI's broader plans for disseminating the results of its funded studies and has added such language. Currently a draft dissemination and implementation framework and toolkit is posted on PCORI.org; additional updates and planning documents will posted as they are available.	**This draft document outlines PCORI's proposed process for fulfilling its statutory mandate** to develop and implement a process for peer-reviewing its primary research and making research findings publicly available in a form and format useful to patients, clinicians, and others. This process **is envisioned as one element within a far more extensive and integrated effort to disseminate the results of PCORI-funded research** to stakeholders across the healthcare community. We are planning and will **implement this broader dissemination and implementation strategy in close collaboration with the Agency for Healthcare Research and Quality (AHRQ)**, as outlined in our authorizing legislation, as well as through the community of healthcare stakeholders, both individuals and organizations, with whom we and our funded investigators have been engaged since early in PCORI's existence.

What We Heard	PCORI's Response	Specific Language Changes to Draft process
5. Clarify the purpose and approach to the methodological review of the report.	PCORI agrees and has added such language.	**The methodological review is intended to provide final confirmation of the validity of the ongoing PCORI staff review of each project for adherence to PCORI's Methodology Standards, a process undertaken throughout the life of a particular study. If the review finds that the study has methodological flaws not previously identified and addressed, the Awardee will be asked to revise the conclusions or other aspects of the research report to reflect that fact.**
6. Reduce the required reading level of the lay abstract to below 8th grade.	PCORI recognizes the need to disseminate information that is accessible by those with limited health literacy and has modified its requirement for readability accordingly.	Following formal acceptance of the final report, PCORI will create a standardized summary of the study's results for patients and general public with **readability at the 6th grade level**, which will be reviewed and approved by the Awardee.

What We Heard	PCORI's Response	Specific Language Changes to Draft process
7. Assure that the abstract and tables are not prior publication. **10. Harmonize the processes of producing the final report, reporting on ClinicalTrials.gov and publication in the peer-reviewed literature.** **11. Minimize the burden to Awardees.**	PCORI recognizes the importance of these concerns and has taken several steps to address them. These include clarifying that the International Committee of Medical Journal Editors considers the 500-word abstract and results tables referenced in the peer review process document not to be prior publication and that PCORI will work closely with Awardees to see that PCORI's process does not interfere with their fulfilling any other legal or regulatory reporting requirements or impede their ability to publish papers resulting from their funded projects.	PCORI's plan to include within its proposed process an approach developed by the National Institutes of Health to implement the Food and Drug Administration Amendments Act (FDAAA) through the National Library of Medicine's clinical trials registry (ClinicalTrials.gov), one that journal editors generally accept as not constituting prior publication. **Registration is a documented milestone** in the contract between the Awardee and PCORI. The **date when results tables are submitted is a recorded milestone** in the Awardees contract with PCORI. The Awardee Institution must submit **a draft final report to PCORI on a date established and recorded as a milestone** in the contract with PCORI. The date may not exceed 13 months from the primary completion date.
8. Add the requirement of a formal evaluation of the process in one year.	PCORI agrees with this suggestion and has added such language to the process document.	**This process will undergo a formal review one year after adoption, with additional review and revision as appropriate in future years to assess how well it is functioning and consistent with PCORI's authorizing law.**

PCORI's Proposal for Peer Review

1. **Registration***. PCORI research projects must be registered at the public site appropriate to study design: ClinicalTrials.gov, Registry of Patient Registries (RoPR), HSRProj, or other as approved. **Awardee and PCORI agree on a primary completion date that is recorded in the contract and in the ClinicalTrials.gov profile.**
2. **Submit results to ClinicalTrials.gov*,** which generates results tables. This only applies to studies registered in ClinicalTrials.gov or RoPR.
3. **Draft Final Report***. Awardee Institution submits draft final report to PCORI for peer review. The due date may not exceed 13 months from the primary completion date.
4. **PCORI Peer Review**. PCORI conducts peer review with a methodologist and/or biostatistician, external subject matter experts, and patient, caregiver, and/or consumer.

*Contract milestone

PCORI's Proposal for Making Research Findings Publicly Available

1. **Preparation of results summaries for patients and general public.** After PCORI accepts the final report, PCORI, with approval of Awardee, produces a summary of the abstract to *"convey the findings of research in a manner that is comprehensible and useful to patients and providers in making health care decisions."*

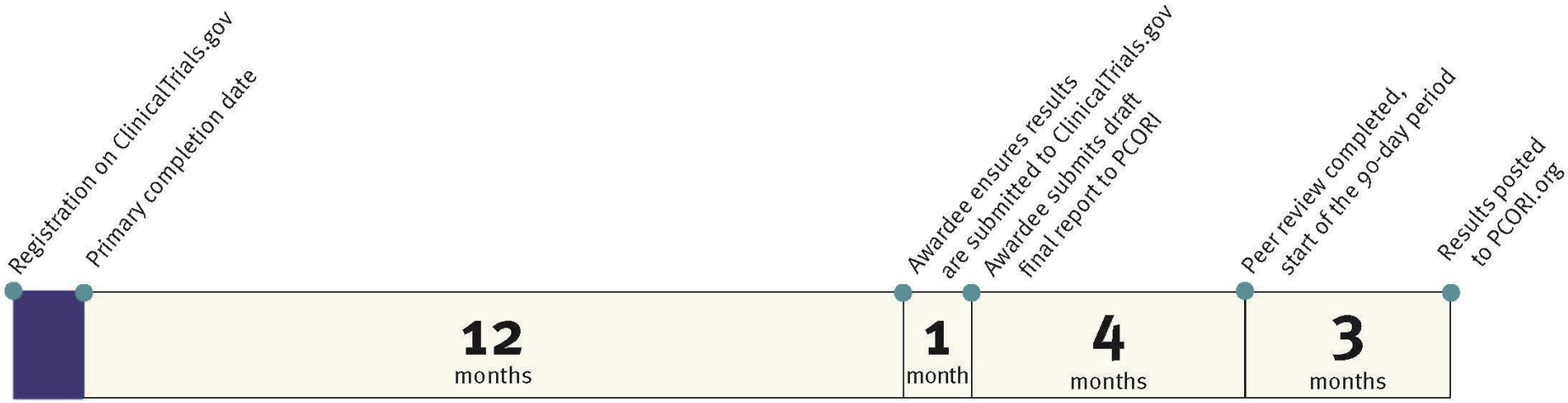
2. **Post to PCORI.org** within 90 days of PCORI's acceptance of final report:
   - PCORI will post the 500-word abstract for medical professionals; the 500-word summary for patients and general public; links to ClinicalTrials.gov results tables; ancillary information; anonymized peer review comments, Awardees' responses, and a process summary.
   - Awardee must ensure that links to the abstracts are submitted to ClinicalTrials.gov, including links to material on PCORI.org.*

** PCORI peer review will include review of results tables submitted to and posted by ClinicalTrials.gov.*

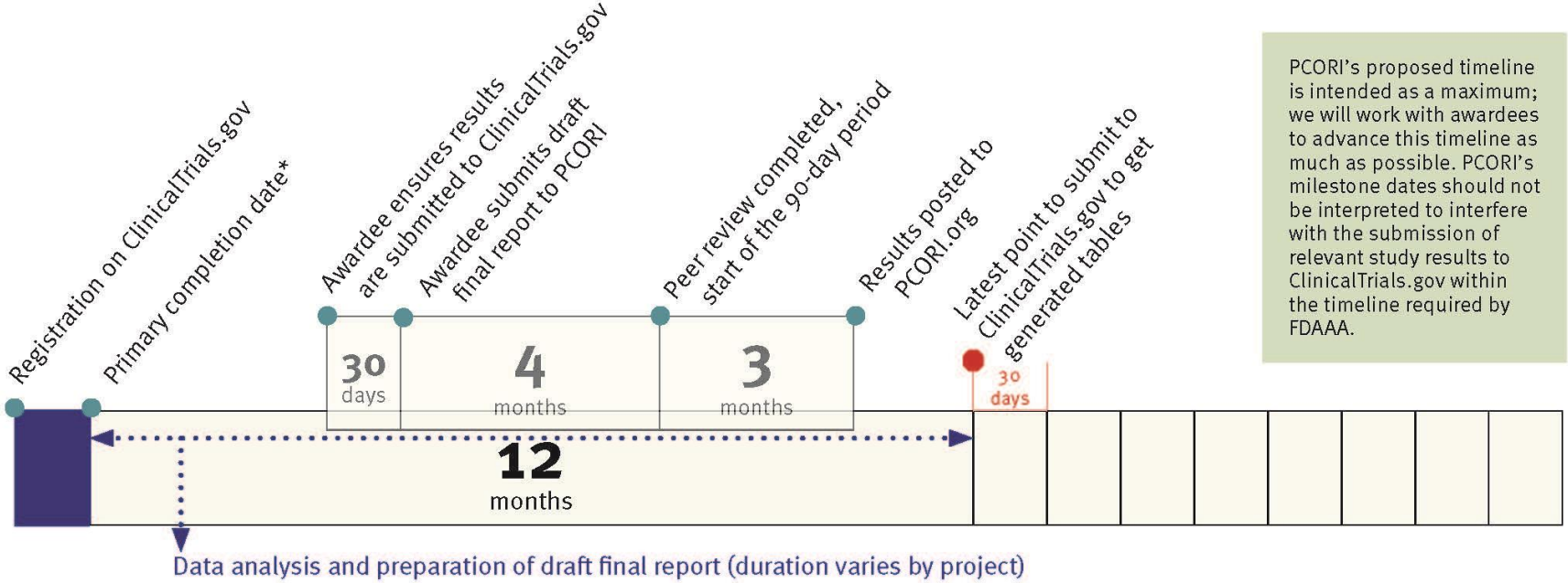
Highlighting Publications and Final Reports

- Investigators are free to publish in journal of their choice at any time.
- Investigators must notify PCORI of manuscripts submitted to journals and accepted for publication. Parallel reviews at investigators' discretion.
- PCORI posts full final report after 12 months from the date of acceptance of the final report, by mutual agreement.
- Reports are discoverable in PubMed and can be assigned digital object identifiers for tracking/citation, addressing concerns about publication bias, lack of reports of negative results and/or failed studies.

Model 1: PCORI Process Follows End of Maximum FDAAA Timeline



Model 2: Milestone-Driven Timeline (PCORI's Proposal)



PCORI's proposed timeline is intended as a maximum; we will work with awardees to advance this timeline as much as possible. PCORI's milestone dates should not be interpreted to interfere with the submission of relevant study results to ClinicalTrials.gov within the timeline required by FDAAA.

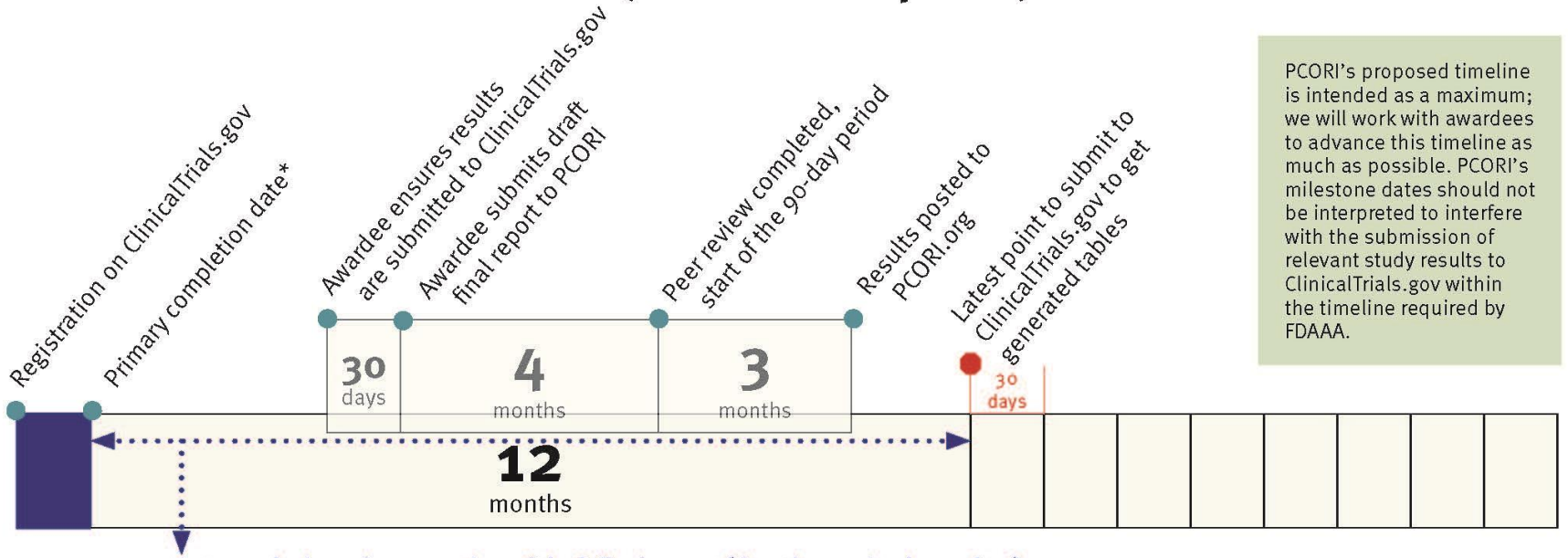
NOTES

duration varies by project

** Primary completion date is the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.*

Results posted to PCORI.org include lay and professional abstracts, ClinicalTrials.gov results tables, and ancillary information, as well as comments from peer reviewers and awardee responses to them.

Milestone-Driven Timeline (PCORI's Proposal)



PCORI's proposed timeline is intended as a maximum; we will work with awardees to advance this timeline as much as possible. PCORI's milestone dates should not be interpreted to interfere with the submission of relevant study results to ClinicalTrials.gov within the timeline required by FDAAA.

NOTES

duration varies by project

** Primary completion date is the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.*

Results posted to PCORI.org include lay and professional abstracts, ClinicalTrials.gov results tables, and ancillary information, as well as comments from peer reviewers and awardee responses to them.

Board Vote: Peer Review and Release of Research Findings Policy

Call for a Motion to:	• **Adopt** the revised Proposal for Peer Review of Primary Research and Public Release of Research Findings
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

Grayson Norquist, MD, MSPH
Chair, Board of Directors

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