

Post Award: PCORI's Process for Peer Review of Primary Research and Public Release of Research Findings

Orlando Gonzales

Chief of Staff for Engagement

June 30, 2015, 11:30 a.m. EDT

July 6, 2015, 1:00 p.m. EDT

July 28, 2015, 11:30 a.m. EDT

Welcome!



Orlando Gonzales, MPA
Chief of Staff, Engagement

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

- Harold Sox, MD
- Bill Silberg
- Joe Selby
- Mary Hennessy
- Jean Slutsky
- Thomas Workman and AIR staff
- Marla Bolotsky and web team
- Blake Whitney
- Emily Evans



In This Session

- PCORI's obligations under its authorizing legislation
- Development process
- Process and timeline
- Milestones



PCORI's Obligation Under its Authorizing Legislation

Conduct Peer Review of Primary Research

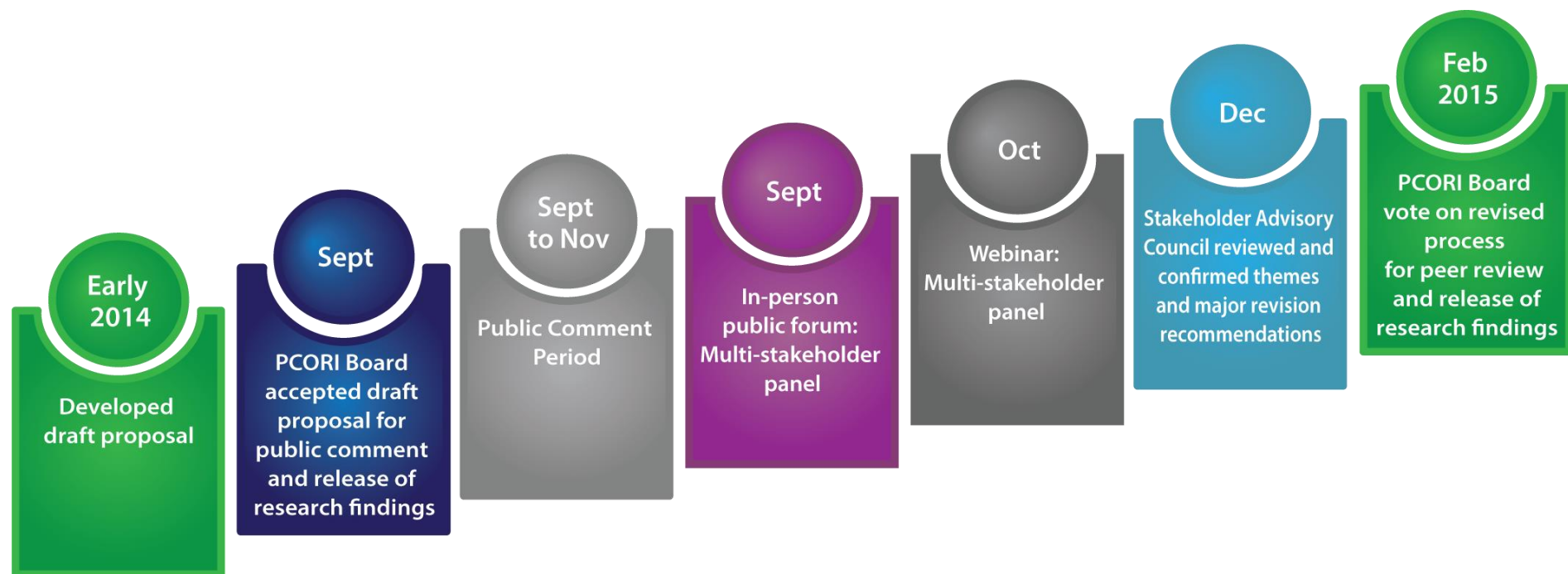
- Assess scientific integrity
- Assess adherence to PCORI's Methodology Standards

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



Development of the Process



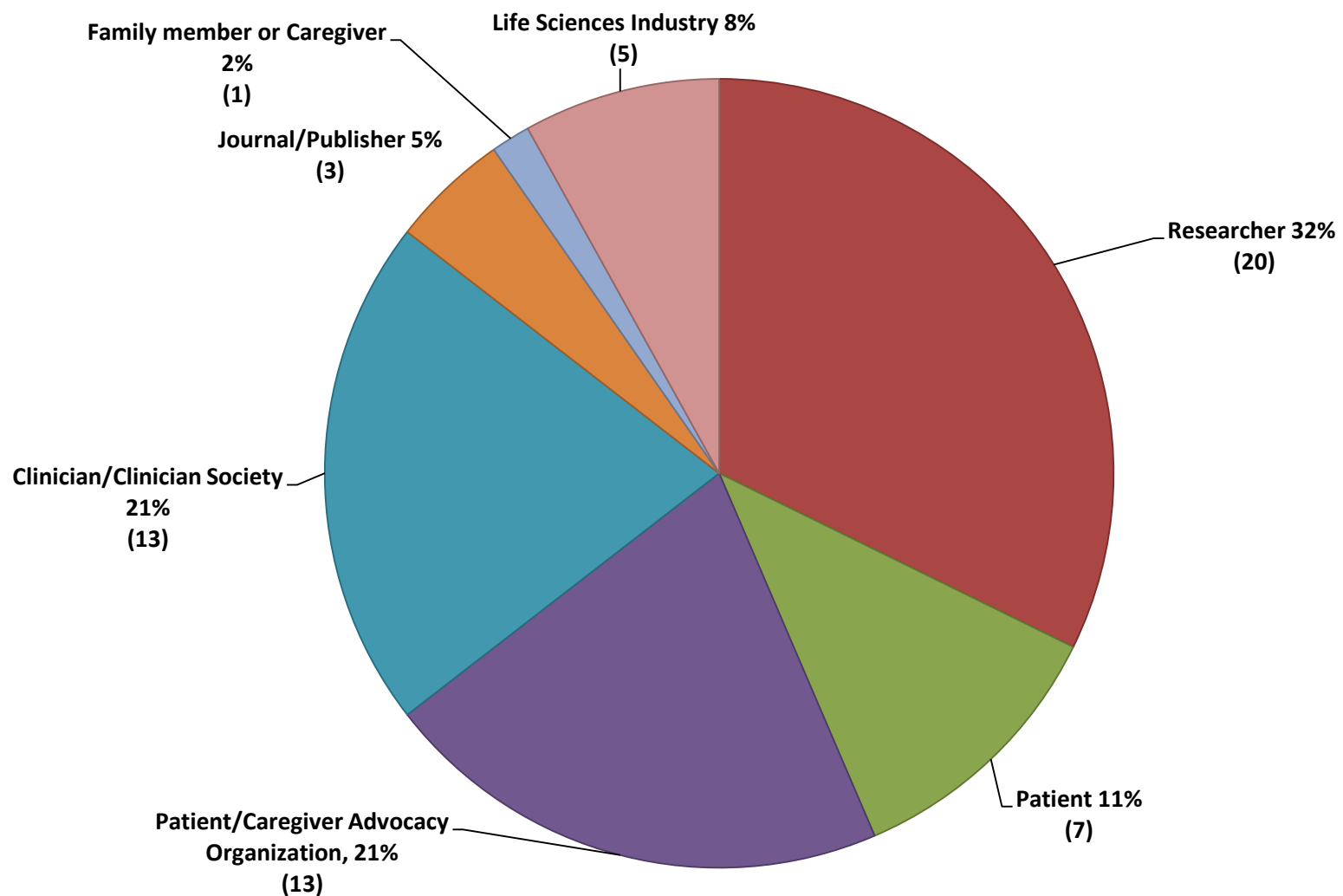
Total Collected Submissions/Comments

Total submissions: 63

Total Comments: 832



Submissions by Stakeholder Category (n=63)



Organizations Submitting Comments

Clinician/Professional Organizations

- American Academy of Family Physicians
- American College of Physicians
- American Nurses Association
- American Nursing Informatics Association (ANIA)
- American Occupational Therapy Association (AOTA)
- American Thoracic Society
- American Society of Health-System Pharmacists
- Association of American Medical Colleges
- Association of American Physiatrists
- Association of Rehabilitation Nurses
- College of American Pathologists
- Deans of Nursing Schools Coalition
- Society of General Internal Medicine
- Wound Ostomy and Continence Nurses' Society
Center for Clinical Investigation

Journal/Publisher

- *Annals of Family Medicine*
- *BMJ*
- *PLOS Medicine*

Life Sciences Industry

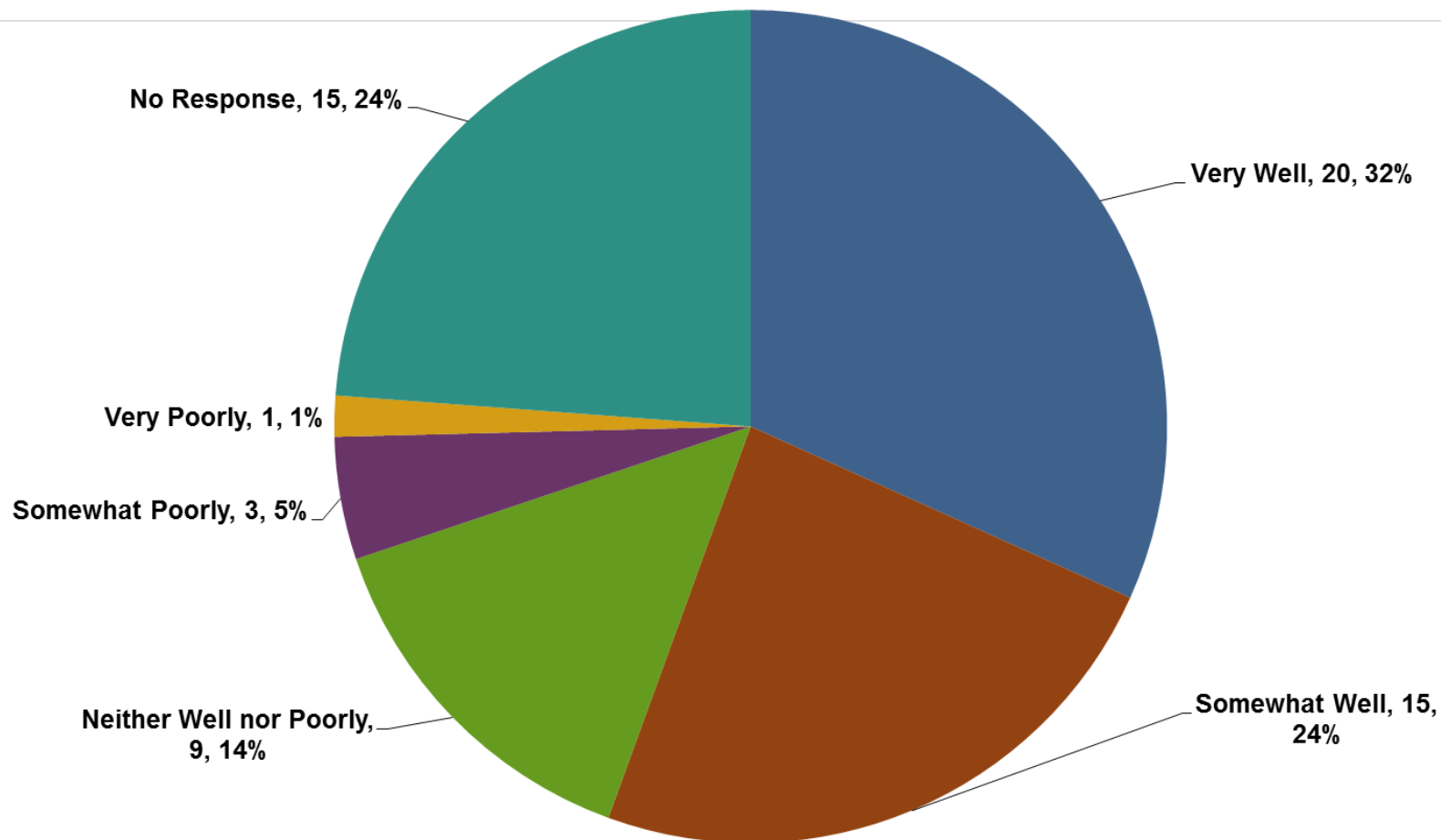
- Advanced Medical Technology Association (AdvaMed)
- Biotechnology Industry Organization
- GlaxoSmithKline
- Pharmaceutical Research and Manufacturers of America
- National Pharmaceutical Council

Patient/Caregiver Organizations

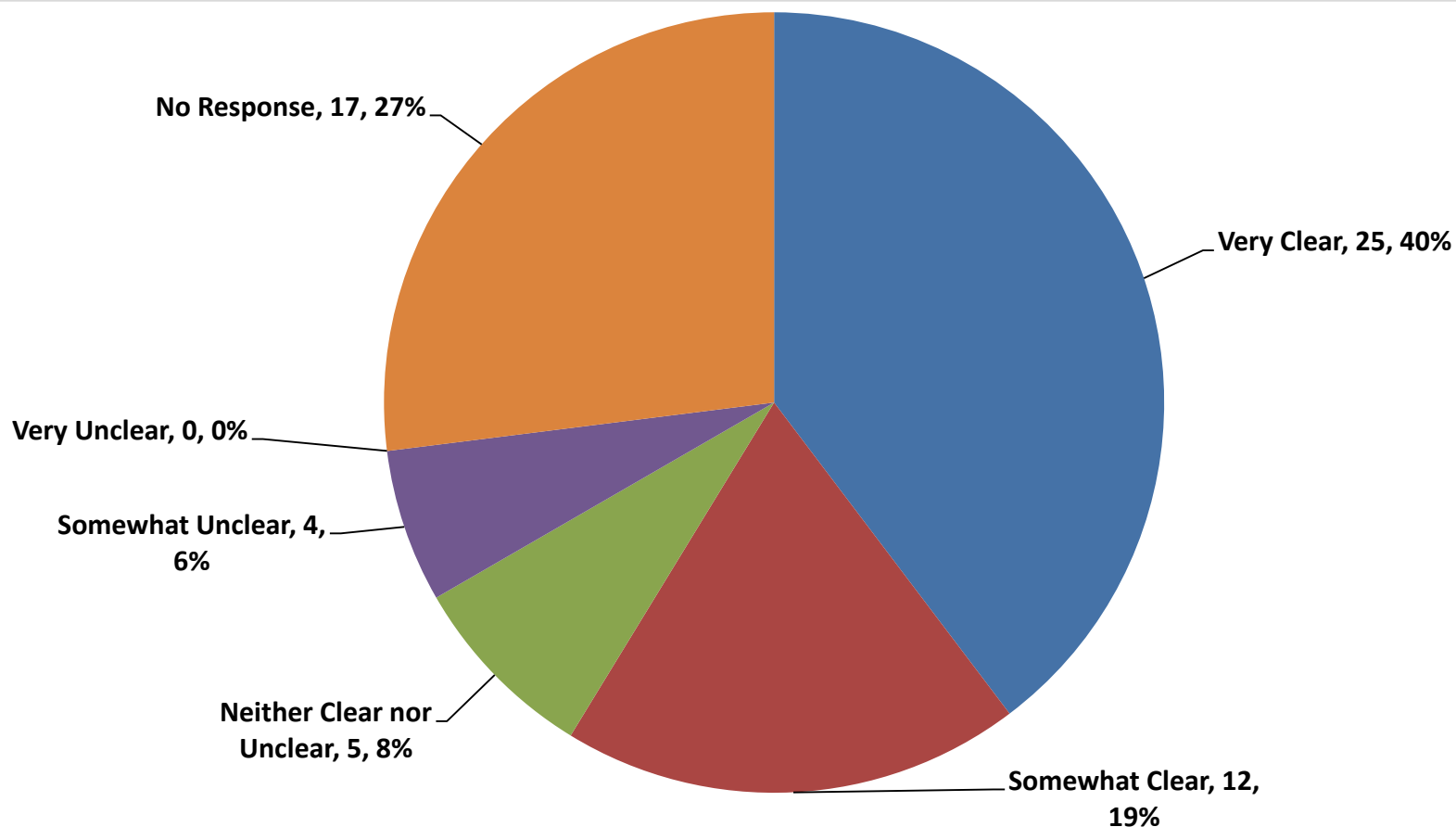
- AllTrials Campaign
- American Cancer Society Action Network
- CaReNet
- Consumer Reports
- Community Campus Partnerships for Health
- March of Dimes Foundation
- National Alliance on Mental Illness
- National Health Council
- National Consumers League
- National Family Caregivers Association
- ThinkWell & Empower2Go



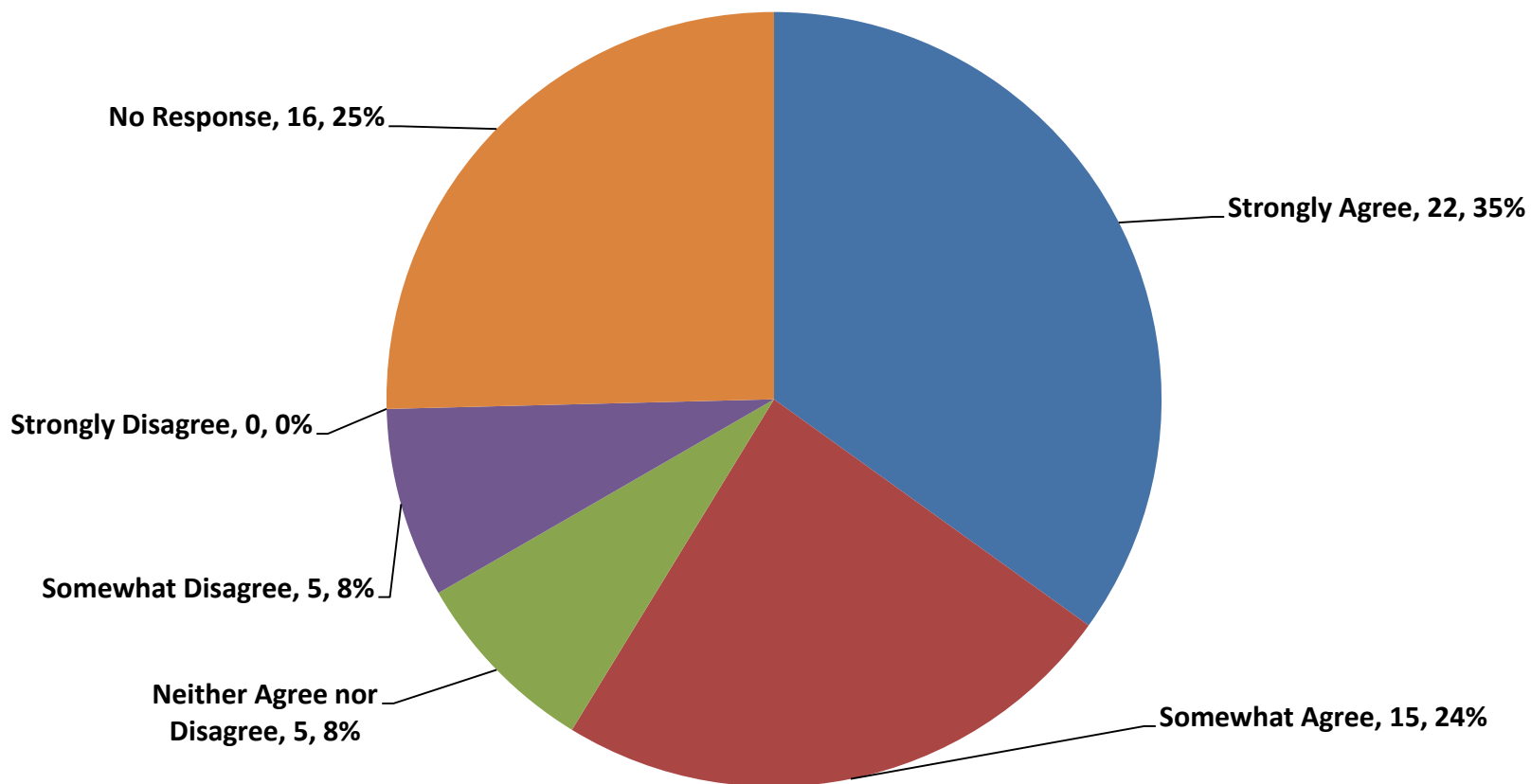
How Well the Proposal Meets PCORI's Obligations Under its Authorizing Legislation



How Well the Proposal Provides a Clear Understanding of the Peer Review and Public Release Process



Do You Agree with the Sequencing of the Peer Review and Public Posting of Results Process



Principles and Definitions

Peer Review

Ensure that results of our funded projects are scientifically sound and meet methodological standards and that risks and limitations are clearly identified

Release of Research Findings

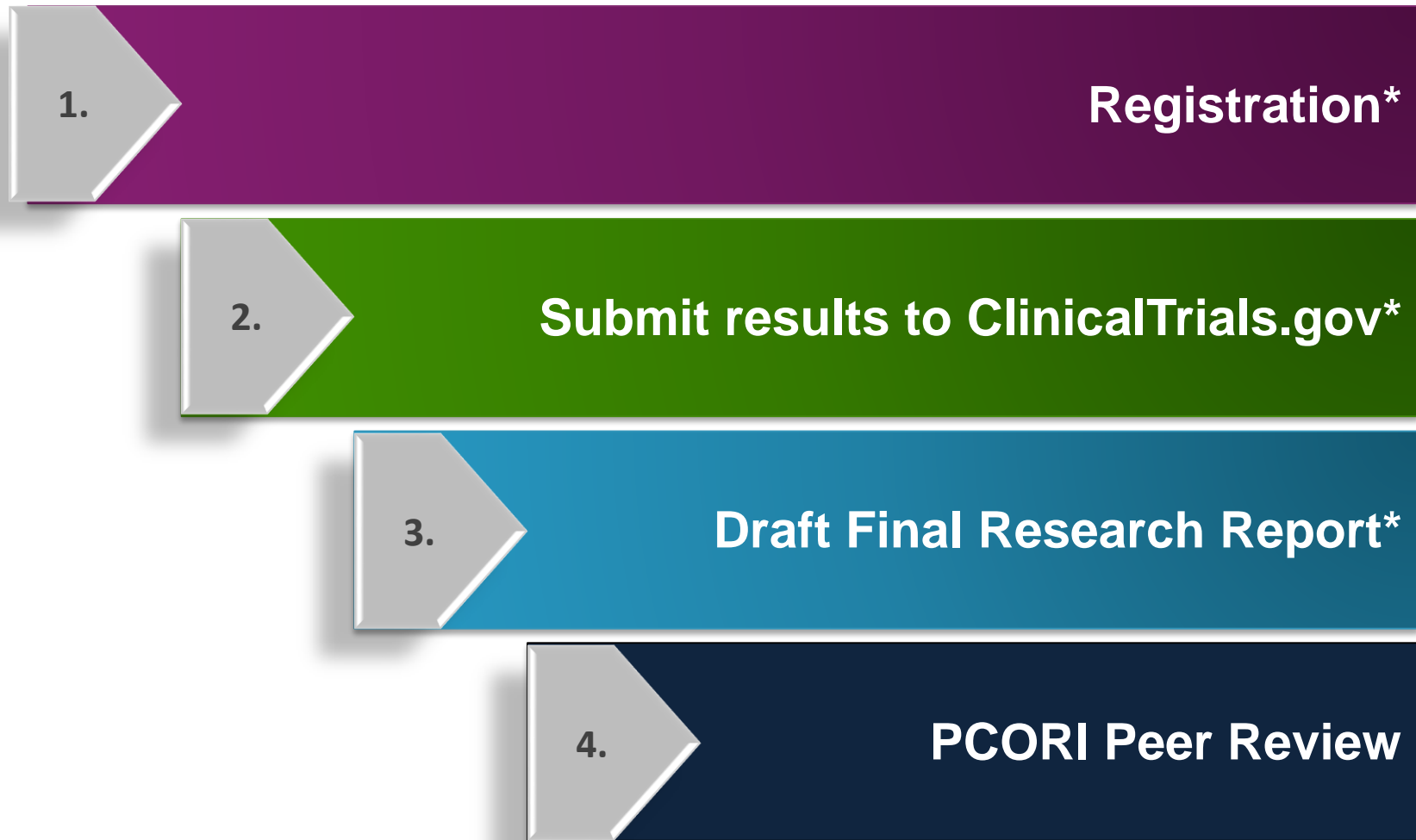
Speed the process of providing valid, useful clinical information to patients, clinicians, and others in an effort to improve decision making

Primary Completion Date

Date last study participant was examined or received an intervention and that data for the primary outcome measure were collected. Primary completion date is a term used on ClinicalTrials.gov for "completion date" (Section 801, Food and Drug Administration Amendments Act of 2007). For studies not eligible to be registered on ClinicalTrials.gov, the Awardee and PCORI shall agree on a primary completion date as a milestone that precedes the agreed-upon date to submit a draft final report (which will be no later than 13 months from the primary completion date).



PCORI's Process for Peer Review



*Contract Milestone



PCORI's Peer Review Process

1.

Registration*

PCORI-funded research projects must be registered at the public site appropriate to study design: ClinicalTrials.gov, Registry of Patient Registries (RoPR), Health Services Research Projects in Progress (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.**



PCORI's Peer Review Process

1.

Registration*

2.

Submit results to ClinicalTrials.gov*

Submit results to ClinicalTrials.gov*, which generates results tables. This only applies to studies registered in ClinicalTrials.gov or RoPR.

*Contract Milestone



PCORI's Peer Review Process

1.

Awardee Institution submits draft final research report to PCORI for peer review. The due date may not exceed 13 months from the primary completion date.

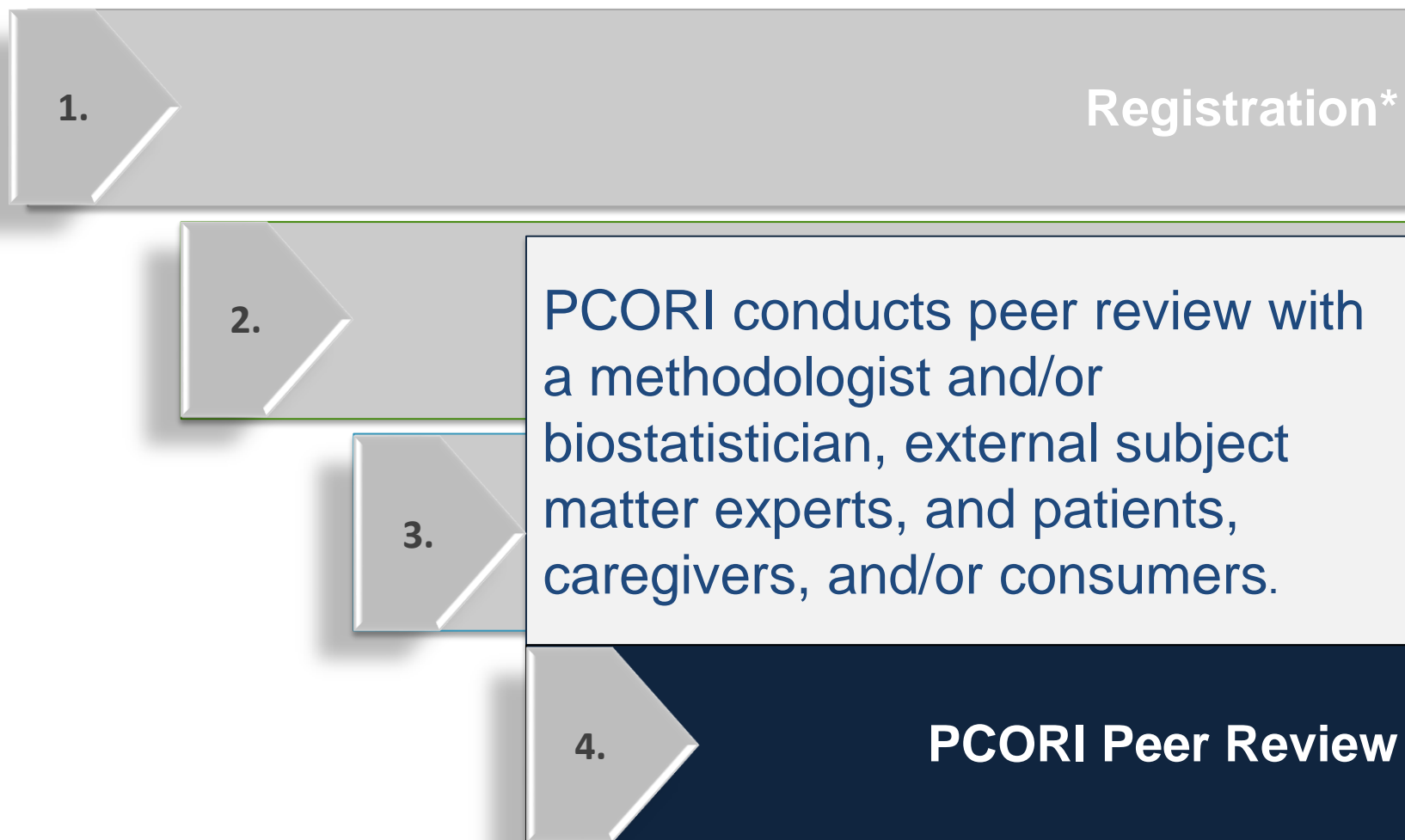
2.

3.

Draft Final Research Report*



PCORI's Peer Review Process

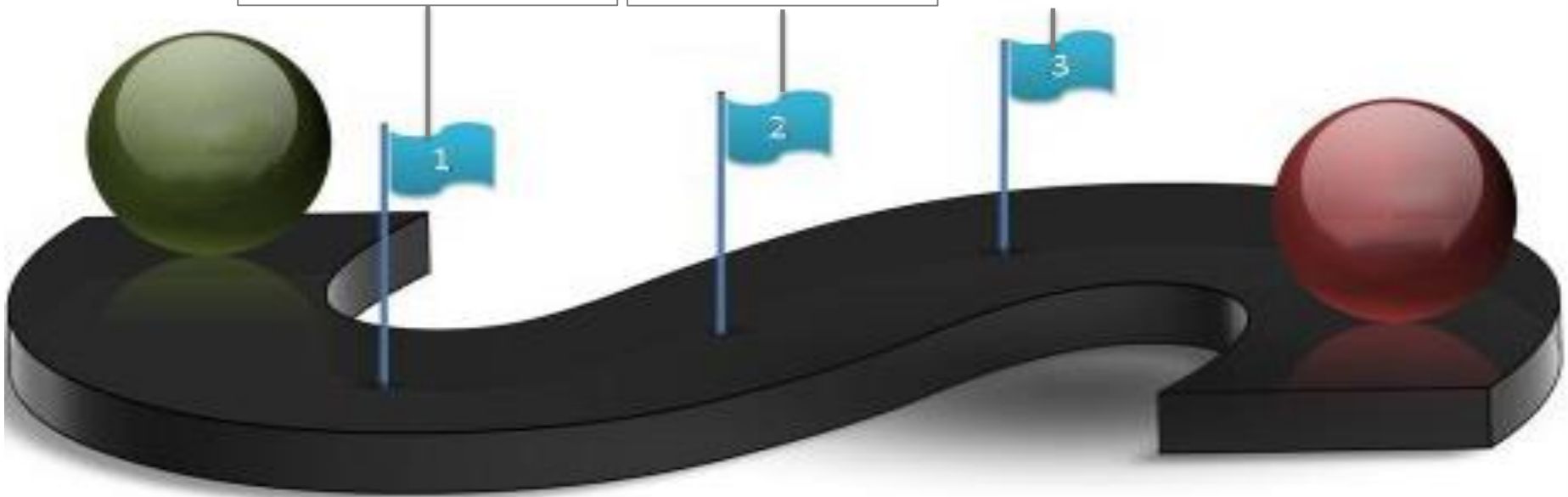


PCORI's Process for Making Research Findings Publicly Available

**Preparation of
results
summaries for
patients and
general public**

**Approval of
Summaries**

**Post to
PCORI.org**



PCORI's Process 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:
 - 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 a journal of their choice at any time.

PCORI posts full final report 12 months after the date of acceptance of the final report, by mutual agreement.

Investigators must notify PCORI of manuscripts submitted to journals and accepted for publication. Parallel reviews at investigators' discretion.

Posted 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.



Milestones in the Research Contracts

Note: Existing PCORI contracts are being modified for time and budget to allow for the peer review process.



Study registration at Clinicaltrials.gov, RoPR, HSRProj, and/or other databases as approved by PCORI before study start date

Primary Research Completion Date

Results submission to ClinicalTrials.gov or appropriate database, if required

Draft Final Research Report submission

PCORI Peer Review summary submitted to awardee and PI

Final Research Report submission



Milestones in the Research Contracts (cont'd.)

Note: Existing PCORI contracts are being modified for time and budget to allow for the peer review process.



PCORI drafts lay summary

Awardee approves lay summary

PCORI posts lay and medical summary and other elements of Final Research Report





Funding Opportunities

WHAT & WHO WE FUND

HOW TO APPLY

APPLICANT TRAINING

WHAT WE MEAN BY
MANAGEMENT

PEER REVIEW PROCESS

GRAMMATIC FUNDING

AWARDEE RESOURCES

POST-AWARD FAQs

Awardee Resources



The resources below are provided to PCORI funded recipients as required by the terms of their PCORI-funded research contract. The resources are applicable to the various funding cycles and include templates by award cycle that will be used to report various administrative, financial, and programmatic updates to the status of projects.

This reporting allows PCORI to successfully monitor the performance of the research projects to ensure adherence to deliverables, milestones, and other requirements described in your PCORI-funded research contract.

Reporting Templates

- [Appendix A: Interim Progress Report](#) *
 - [Summary of Changes to the Interim Progress Report](#)
- [Appendix B: Final Report](#)
- [Appendix C: Expenditure Report Template](#)
- [Sample Invoice Template](#)
- [Standard Contract for Funded Research Projects](#)

* This document was updated on June 25, 2015

Peer Review and Public Release of Research Findings

By law, all PCORI-funded primary research must undergo peer review and all results must be made available to the public. The first document explains PCORI's process for conducting peer review and releasing the research findings and the second provides instructions for awardees in developing the draft final research report that will undergo peer review.

- [Process for Peer Review of Primary Research and Public Release of Research Findings](#)
- [Draft Final Research Report: Instructions for Awardees](#)

GLOSSARY

HELP CENTER



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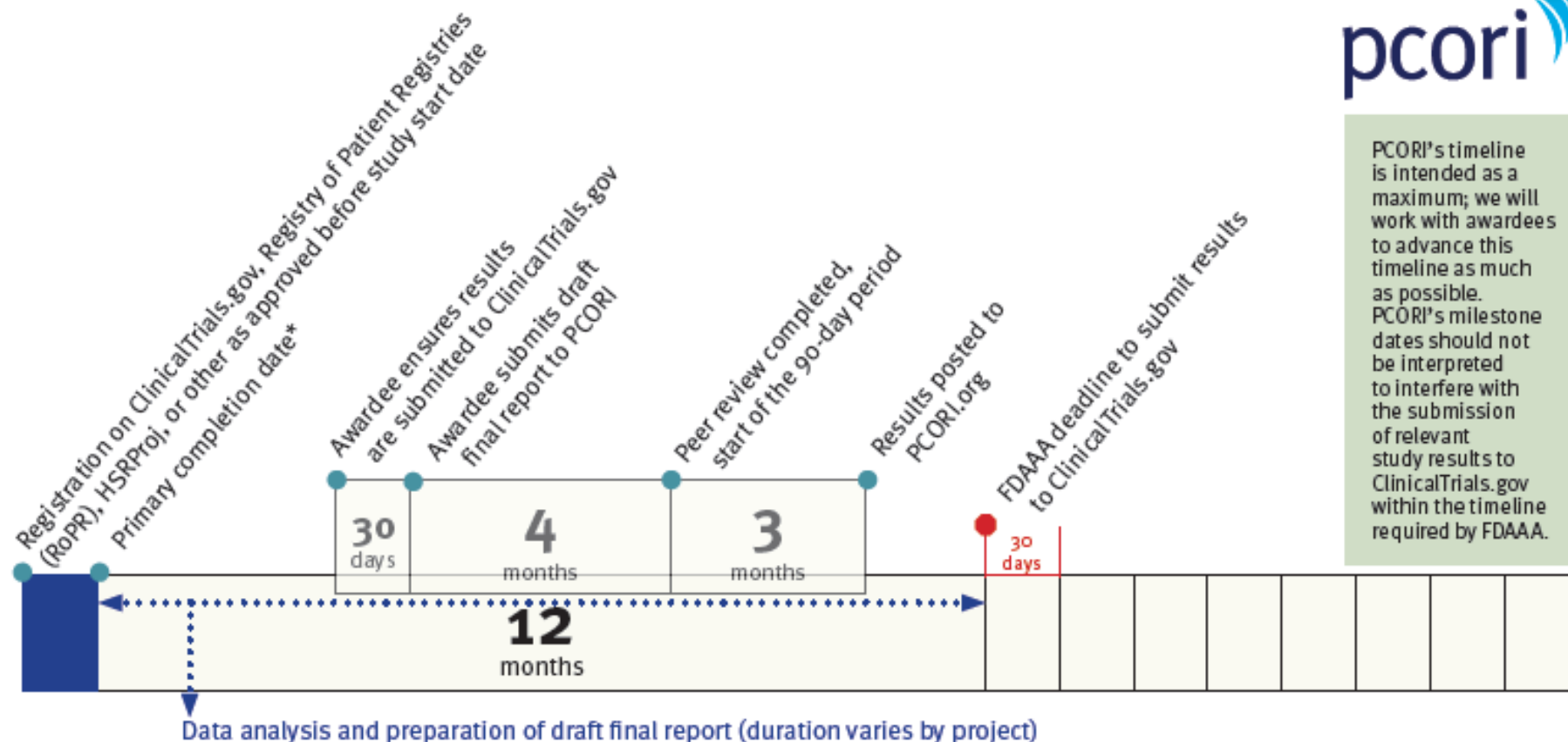
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Milestone-Driven Timeline



PCORI's 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 the final subject [or participant] was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the study concluded according to the prespecified protocol or was terminated. The "estimated primary completion date" is the date that the researchers think will be the primary completion date for the study. The primary completion date is the term currently used on ClinicalTrials.gov for "completion date" defined in Section 801 of the Food and Drug Administration Amendments Act of 2007. For studies that are not clinical trials or observational studies registered on ClinicalTrials.gov, the Awardee Institution and PCORI shall agree on a primary completion date as a milestone that precedes the agreed-upon date to submit a draft final report. The milestone to submit a draft final report may be no later than 13 months from the primary completion date.

Questions?



Orlando Gonzales, MPA
Chief of Staff, Engagement



Enas Areiqat
Contracts Manager, Post Award



Bill Silberg
Director, Communications



Scott Solomon, MBA, MSE
Director, Contracts Management
and Administration



Thank You!



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