

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

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Welcome!



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In This Session

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



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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

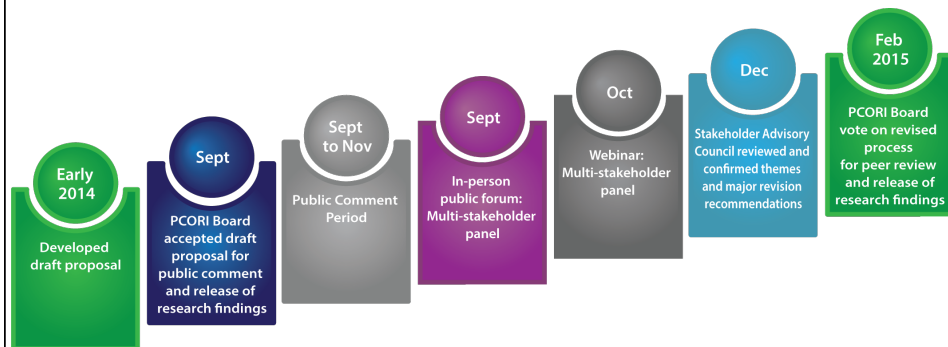
- No later than 90 days after "conduct or receipt"
- Make available to clinicians, patients, and general public
- Make comprehensible and useful to patients and providers for healthcare decisions
- Include considerations specific to certain sub-populations, risk factors, and comorbidities
- Describe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



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Development of the Process



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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).



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PCORI's Process for Peer Review



PCORI's Peer Review Process



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



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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*

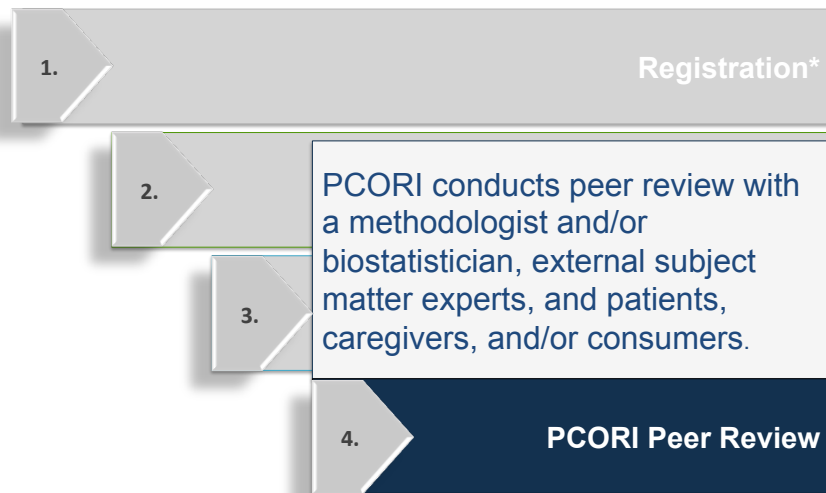
*Contract Milestone



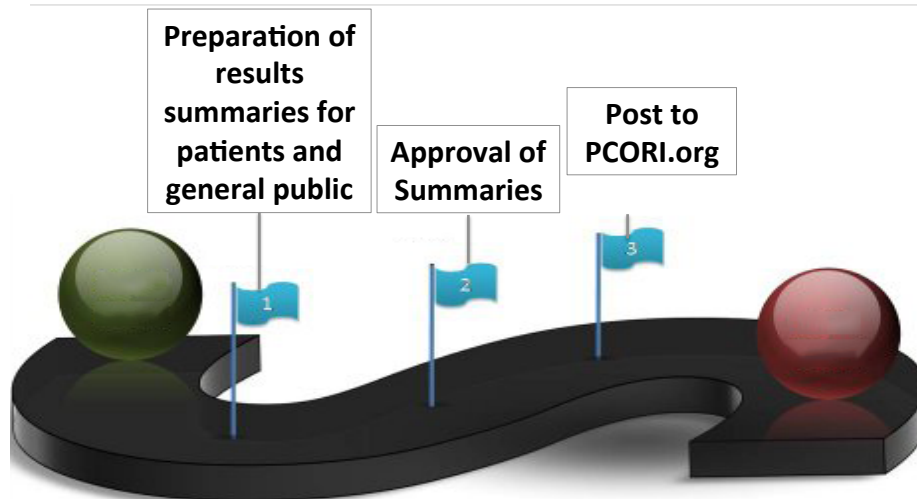
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PCORI's Peer Review Process



PCORI's Process for Making Research Findings Publicly Available



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

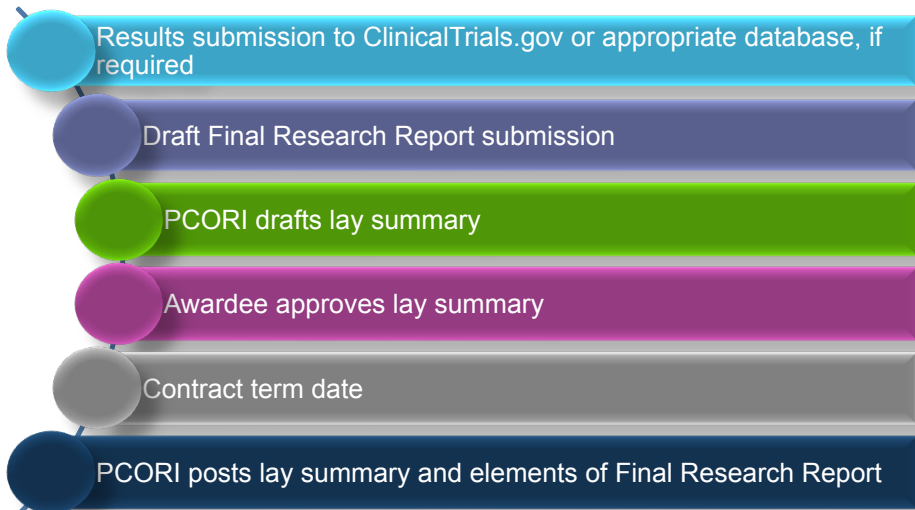
PCORI Peer Review summary submitted to awardee and PI

Final Research Report submission



Milestones in the Research Contracts (cont'd.)

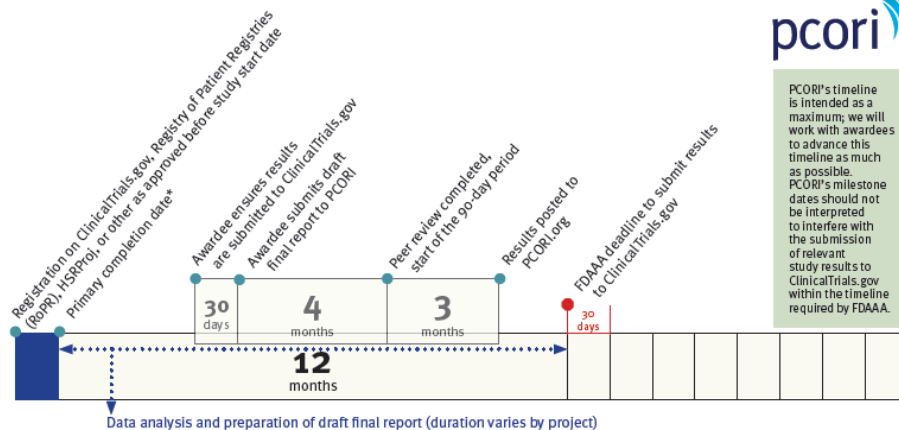
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Milestone-Driven Timeline



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?



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Thank You!

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