PCORI Predictive Analytics Resource Center (PARC)

REQUEST FOR PROPOSAL

RFP # PCO-PARC 2017

September 19, 2017

<table>
<thead>
<tr>
<th>KEY DATES</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Request for Proposal Released</td>
<td>September 19, 2017</td>
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<tr>
<td>Deadline for Questions</td>
<td>September 29, 2017</td>
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<tr>
<td>Deadline for Proposals</td>
<td>October 27, 2017</td>
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<tr>
<td>Projected Award Date</td>
<td>December 1, 2017</td>
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<td>Projected Start Date</td>
<td>December 22, 2017</td>
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</tbody>
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About PCORI

PCORI was authorized by the Patient Protection and Affordable Care Act of 2010 as a non-profit, nongovernmental organization and is charged with helping patients, clinicians, purchasers, and policy makers make better-informed health decisions by “advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions.” It does this by funding research guided by patients, caregivers, and the broader healthcare community, which results in high-integrity, evidence-based information.

PCORI’s strong patient-centered orientation directs attention to individual and system differences that may influence research strategies and outcomes. PCORI is charged with producing useful, relevant clinical evidence through the funding of new research and the analysis and synthesis of existing research.

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI uses a variety of forums and public comment periods to obtain public input to enhance its work.
Opportunity Snapshot

The Patient-Centered Outcomes Research Institute (PCORI) is seeking a Contractor to enter into an agreement to serve as a PCORI Predictive Analytics Resource Center (PARC). The Contractor shall provide the following types of professional services/support to PCORI:

- Production of a white paper to assist PCORI in understanding the current state of the science in the development of appropriately rigorous and focused research projects that use predictive analytic techniques to analyze or reanalyze research data to determine when and how to target interventions to maximize benefit and/or minimize harm or cost. The white paper will:
  1. Outline key methodological issues that should be considered when conducting robust, reliable analyses using validated risk prediction tools or other approaches;
  2. Elucidate criteria and statistical or other approaches to inform the identification of topic areas and/or clinical datasets that are most likely to yield clinically meaningful differentiation of intervention results through predictive analytics, and the recommended approaches for determining the most valid and useful predictive approach; and
  3. Outline key issues for appropriately qualifying the reported results of these analyses (including articulation of future research needs) to inform their appropriate dissemination to healthcare decision-makers, including patients, caregivers, and the public.

- Formal input into the critical elements and an overall model required to stand up a successful funding system for a new PCORI-funded research portfolio dedicated to predictive analytics. This includes identification of the requirements for minimal technical approaches and resources to be addressed in all applications for funding. Offerors should plan to outline the range of resources necessary for overseeing this program (including suggestions for the identification of promising existing data sources or ongoing projects); these program components should be focused to support all aspects of launching and continuing a successful research portfolio in predictive analytics, and should include estimates of the budgets, expertise, and timelines required for varying types of related research projects. Offerors should expect to elicit and effectively incorporate critical review of their input as needed to ensure the recommendations are rigorous and broadly supportable, with consideration of minimization of potential conflicts of interests from all those providing input.

- Screening of the current PCORI-funded primary research portfolio, to identify potentially promising topics for predictive analytic work that would benefit from supplemental funding awards.
• Consulting and coordination services to support PCORI’s interagency activities (e.g., between PCORI and the FDA or NIH) addressing collaborative predictive analytic project opportunities.

As summarized below, PCORI also anticipates contracting separately with the Contractor under research project agreement(s) for the completion of pilot predictive analytics research projects. Proposals should be received no later than 5 p.m. (ET) on October 27, 2017. Prospective applicants may submit questions regarding the RFP no later than 5 p.m. (ET) on September 29, 2017.

PCORI expects to make a single award. The Contractor will operate at the direction of and receive guidance from PCORI.
How to Proceed

1. **Review the Requirements**
   Examine all sections of the RFP and learn about what makes PCORI’s research different.¹

2. **Consider the Evaluation Criteria**
   Consider the organization’s eligibility requirements and PCORI’s specific requirements to see whether your organization, your interests, and your capabilities fit the requirements listed in this RFP. Check the PCORI website for any modifications or amendments up to the submission deadline.

3. **Develop Your Proposal**
   Develop your response to the requirements within this RFP.

4. **Follow Submission Guidelines**
   See the Submission Guidelines section of this document.

5. **Submit Your Proposal**
   Proposals are due by 5 p.m. (ET) on **October 27, 2017**.

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¹ Available at pcori.org/research-we-support/pcor
## Contents

About PCORI ................................................................................................................................. ii

Opportunity Snapshot ................................................................................................................... iii

How to Proceed .............................................................................................................................. v

Statement of Work ........................................................................................................................ 1

Purpose ........................................................................................................................................... 1

Specific Requirements .................................................................................................................... 3

### Deliverables ............................................................................................................................. 6

Deliverables Schedule .................................................................................................................... 6

Acceptance of Deliverables .......................................................................................................... 7

Kickoff Meeting ............................................................................................................................. 7

Project Lead’s Authority ................................................................................................................. 8

Period of Performance .................................................................................................................. 8

Type of Agreement ......................................................................................................................... 8

### Proposal Evaluation Criteria ................................................................................................... 9

Technical Approach ....................................................................................................................... 10

Management Plan ......................................................................................................................... 10

Past Performance .......................................................................................................................... 10

Price Proposal ................................................................................................................................ 11

Award without Communications or Clarifications ......................................................................... 12

Best and Final Offers ...................................................................................................................... 12

Withdrawal or Modification of Proposals ....................................................................................... 13

Late Submissions .......................................................................................................................... 13

Retention of Proposals .................................................................................................................. 13

Documentation Requirements ....................................................................................................... 13

Basis of Compensation to the Contractor ..................................................................................... 13

Post-Award Debriefing .................................................................................................................... 13

PCORI RFP # PCO-PARC 2017
Post-Award Information ...................................................................................................... 14
PCORI Rights ..................................................................................................................... 14
Furnishing of Equipment/Property .................................................................................... 14
Place of Performance ....................................................................................................... 14
Hours of Service ................................................................................................................ 14
Insurance ........................................................................................................................... 14
Non-Disclosure and Security Requirements ....................................................................... 14
Potential for Organizational Conflicts of Interest and Personal Conflicts of Interest ............... 15
Compliance ....................................................................................................................... 15
Invoice Content ............................................................................................................... 15
Billing and Payment Procedures ....................................................................................... 16
Submission Guidelines ....................................................................................................... 17
Volume 1: Administrative – Page Limit: None ................................................................. 17
Cost Reimbursable Agreement ....................................................................................... 18
Appendix A: Past Performance Questionnaire ................................................................. 20
Statement of Work

Through this Request for Proposal (RFP), PCORI announces its intention to enter into an agreement for the creation of a PCORI Predictive Analytics Resource Center (PARC) to assist PCORI in efficiently and effectively launching a new funded research portfolio to utilize predictive analytic methods in primary and secondary research, in order to better personalize treatment options for individuals and subpopulations.

PCORI envisions that through this RFP, PCORI will issue an agreement with a single Contractor.

Purpose

PCORI is seeking a Contractor to provide support to PCORI for the development of a new portfolio of funded research activities in the area of predictive analytics that will apply robust methods to appropriate topics in order to determine whether clinically important heterogeneity of treatment effects exists. The ultimate goal of this funded research portfolio is to provide evidence on better-targeted, specific clinical interventions to individuals or subpopulations to maximize their potential to experience benefit and minimize the potential for harm (including waste from the application of ineffective interventions) and to inform comparative choices in clinical treatment, diagnosis, assessment, prevention, and management.

Heterogeneity of treatment effect (HTE)—the idea that the effects of a treatment will differ between subgroups or individual patients—is an important component of comparative effectiveness research, particularly when such research is based in real-world conditions. Ideally, when comparing treatments to one another, one would choose a therapy based on a specific individual’s unique characteristics and his or her likelihood of experiencing potential outcomes (positive and negative) related to the choice of intervention. One of the difficulties faced when interpreting the results of randomized controlled trials in the aggregate is that they typically provide only a summary estimate of the average treatment effect and its statistical variance. However, even in tightly controlled trials, not all individuals will be truly “average,” meaning that the estimated effect size may not capture the intervention’s effect for any given person or even most people. This becomes particularly of concern in pragmatic clinical studies.

whereby participant exclusion criteria are minimized to create “real-world evidence.”5 In this instance, the breadth of the population studied requires careful attention to the consistency of the intervention’s effects across differences in the population as characterized by baseline outcome risk, age, sex, or other characteristics.6 Traditional efforts to look for differences in treatment effect sizes according to individual factors have relied upon one-variable-at-a-time approaches; these methods do not accurately represent the multi-faceted nature of individuals, who obviously are different from one another across multiple variables at a time.7,8 Predictive analytics seeks to move beyond the average effect size and to more accurately represent the diversity of patient heterogeneity, by applying multivariable risk models to evaluate treatment effects across strata defined by baseline outcome risk or other key drivers of heterogeneous responses to treatment.9,10 While other characteristics besides baseline outcome risk can drive treatment effect modification and thereby heterogeneity of treatment impact, baseline risk is the most common concern. This is because, even in the absence of effect modification, absolute risk drives absolute benefit (as well as absolute harms),11 and thus the balance between benefits and harms will vary even when effect modification is not present.12

A new funding program of research activities in the area of predictive analytics is in line with the mission of PCORI to help people make better-informed healthcare decisions by allowing for greater personalization of evidence-based information about available treatment choices based on an individual’s own unique circumstances and characteristics. These analytic methods can be applied to large pragmatic trials as part of their initial planned analyses, or as part of a reanalysis of data from

one or several clinical trials when individual participant data is appropriately combined. By supporting
the reuse of data from previously conducted trials, PCORI will make an efficient and judicious use of
resources. By applying predictive analytics to areas characterized by diverse participants and/or
interventions with important benefit–risk tradeoffs, PCORI can help to optimize the use of clinical
interventions in real-world practice. Predictive analytics can also be particularly helpful in situations
where a wide range of responses to treatment are suspected based on clinical practice or thinking. As
the field matures, PCORI anticipates growing clarity about the types of clinical topics, questions, and
trial designs that are most likely to yield useful clinical results from these types of analyses.

Specific Requirements
The new PCORI PARC will have four (4) major requirements in assisting PCORI to develop a new
predictive analytics research funding program. Additionally, PCORI anticipates an additional separate
requirement relating to completing pilot predictive analytic research projects, as outlined below:

1. The production of a state-of-the-science white paper, the purpose of which would be to define
the most productive areas for the types of analyses related to heterogeneity of treatment effect
and the most critical aspects of appropriate methods for these types of analyses. The paper
must outline a knowledge development pathway that captures the process of analyzing or
otherwise qualifying a potential topic as a likely candidate for important, clinically meaningful
results from using predictive analytic approaches. The paper should explore and describe the
types of clinical research datasets that could be utilized (beyond pragmatic clinical trials), the
optimal clinical characteristics and variables, and the types of topics best suited to predictive
analytic work. Offerors should be prepared to outline a set of principles, criteria, or analyses
that are based on empirical research or expert experience. These should include principles or
sets of criteria that can be applied to focus on funding a research portfolio on the most
productive clinical topics or conditions, research questions, or research approaches for the
application of predictive analytic techniques to determine whether clinical meaningful
heterogeneity of treatment effect exists. Offerors should also expect to document descriptive or
analytical statistics, or sets of criteria, to allow PCORI to determine whether there is sufficient
variation, power, and other key data requirements for robust predictive analyses to determine
heterogeneity of treatment effect in specific clinical research datasets. Offerors should expect to
outline principles to inform an individual project’s development of an appropriate predictive
analytic approach. These will include, but will not be limited to 1) ensuring a robust, hypothesis-
driven set of variables; 2) identifying the appropriate outcome focus for the predictive analytic
approach; and 3) identifying the location and choice of validated tools to predict risk of benefit,
harm, or other important drivers of heterogeneous treatment effects. Similarly, minimal
requirements for the deployment of validated predictive models in these analyses, or for the
development of such models in their absence, and other important caveats for this work should
be captured. The use of various statistics to test model fit and predictive ability should be
covered, with caveats as to their interpretation.
2. Providing formal input into the identification and description of the critical elements and overall structure of a successful funding system for a research portfolio dedicated to predictive analytic research. A successful funding model would identify the requirements and resources necessary to support and encourage the development of new and innovative research in this area (including suggestions for the identification of promising existing data sources or ongoing projects, as well as expertise required for portfolio oversight). This would also include elucidating key components to be addressed in funding applications (e.g., suggested adaptations to PCORI’s research plan template, minimal investigator/team expertise required to be represented in the proposed research team) and concrete estimates of the budgets and timelines that would likely be required for the different types of research projects that could potentially be funded under this program. Other important elements to address include, but are not limited to, funding agency expertise, any recommended adjustments for merit review of applications, and an estimate of the level of interest and degree of scientific expertise available in the U.S. research community. The Offeror should plan to produce a recommended approach that could be incorporated into PCORI’s existing funding announcements for large pragmatic and targeted studies beginning in Fall 2018, that outlines PCORI’s interest in and requirements for predictive analytic approaches in appropriate proposed clinical trials, in addition to outlining a separately focused program of research using already existing clinical research data.

As a function of this requirement, Offerors should expect to both elicit and incorporate critical peer review of their input by PCORI’s Methodology Subcommittee as well as potential outside experts as needed to ensure that the recommendations are rigorous and broadly supportable. Consideration should be given to the minimization of potential conflicts of interest from all those providing input on these elements.

3. The development and use of a systematic, transparent screening method for the currently funded PCORI-funded research portfolio, to identify potentially promising projects as candidates for new predictive analytic work to be funded by PCORI through supplemental research awards. The Offeror should expect to deploy information such as that developed and articulated in the white paper (Task 1) with consideration of timing and cost issues as outlined in Task 2 in this process. The Offeror will produce a qualified list of ongoing studies along with a brief description of the key issue(s) of interest and uncertainty in regard to heterogeneity of treatment effect for each. The production of this list should be timed to be finalized before the end of FY 2018 (September 30, 2018).

4. The provision of consulting and coordination services to PCORI to support PCORI’s interagency activities (e.g., PCORI and FDA, PCORI and NIH) that address collaborative opportunities for predictive analytic projects. The Offeror will make available the requisite clinical, statistical, and other research expertise to support PCORI’s efforts to engage with other funders or regulatory agencies to expand the use of these types of methodologies in order to produce clinically meaningful, targeted research results for application in clinical decision-making. The Offeror
should anticipate supporting bimonthly meetings (twice a month) with various partners that will include educational outreach, including case examples. The Offeror will also help to identify and develop specific areas for collaborative research focus, as well as other activities necessary to develop collaborative partnerships in PCORI’s research agenda.

5. In addition to providing resource support services, PCORI anticipates contracting separately with the Predictive Analytics Resource Center under research project agreement(s) to conduct three pilot predictive analytic research projects during its initial period taking into account the collaborative agency efforts or via other mechanisms for identifying important demonstration projects.

PCORI encourages the Offerors to reflect an understanding of the attributes mentioned above in their proposals. PCORI will assess the performance of the Offerors according to the criteria established in this RFP.
Deliverables

All deliverables must be completed and include, but are not limited to, the following. Each deliverable shall be provided to PCORI.

1. Kickoff call with agenda, follow-up minutes, and action items.
2. Interim status report.
3. Draft white paper. Final white paper that takes into account PCORI feedback.
4. Document outlining the major elements and proposed structure of a PCORI funding system that would optimally foster and support a robust research portfolio in the area of predictive analytics.
5. List of PCORI data sources (from the currently funded PCORI research portfolio) potentially ready for secondary predictive analysis work, along with brief descriptions of the salient issue(s) of interest in regard to heterogeneity of treatment effect for each and the overall method for screening PCORI’s portfolio for qualified candidates.
6. Final project report.

Deliverables Schedule

The following sample Deliverables Schedule is presented for informational purposes only.

<table>
<thead>
<tr>
<th>Deliverable</th>
<th>Description</th>
<th>Quantity/Media</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Kickoff call</td>
<td>Summary of call</td>
<td>Within 1 week of agreement execution</td>
</tr>
<tr>
<td>2</td>
<td>Interim status report</td>
<td>Summary of progress on contract milestones</td>
<td>At 6 months after agreement execution</td>
</tr>
<tr>
<td>3</td>
<td>Draft white paper</td>
<td>One report in MS Word</td>
<td>Four months after agreement execution</td>
</tr>
<tr>
<td>4</td>
<td>Final white paper</td>
<td>One report in MS Word and PDF</td>
<td>Six weeks after receiving PCORI feedback on draft</td>
</tr>
<tr>
<td>5</td>
<td>Document outlining the major elements and proposed structure of a PCORI funding system for a research portfolio on predictive analytics</td>
<td>One report in MS Word</td>
<td>Twelve months after agreement execution</td>
</tr>
<tr>
<td>Deliverable</td>
<td>Description</td>
<td></td>
<td></td>
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<tr>
<td>-------------</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>List of PCORI data sources potentially ready for secondary predictive analysis work, along with brief descriptions of the salient issue(s) of interest in regard to heterogeneity of treatment effect for each and overall method for screening portfolio for qualified candidates.</td>
<td></td>
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<tr>
<td>7</td>
<td>Task 4 deliverables</td>
<td></td>
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</tr>
<tr>
<td>8</td>
<td>Final report</td>
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</table>

<table>
<thead>
<tr>
<th>Quantity/Media</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>One report in MS Word or MS Excel</td>
<td>Sixteen months after agreement execution</td>
</tr>
<tr>
<td>TBD</td>
<td>TBD</td>
</tr>
<tr>
<td>Final summary of execution of agreement milestones</td>
<td>End of agreement</td>
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### Acceptance of Deliverables

PCORI shall provide the Contractor with written acceptance or rejection (with specified reasons). The Contractor will have seven (7) business days to complete and deliver changes made as a response to PCORI’s comments unless otherwise specified in the Deliverables Schedule. The Contractor shall be allowed one re-submission of a deliverable.

### Kickoff Meeting

The Contractor shall work with PCORI to schedule and coordinate a Project Kickoff Meeting at the PCORI office or via a conference call. The meeting will provide an introduction between the Contractor personnel and PCORI personnel who will be involved with the agreement. The meeting will provide the opportunity to discuss technical, management, and reporting procedures. At a minimum, the attendees shall include key Contractor personnel and PCORI’s Procurement Department and Project Lead (PL). The Contractor shall provide the following at the Kickoff Meeting:

- Introduction of personnel
- Overview of tasks and deliverables
- Schedule
- Invoice procedures
- Reporting requirements, e.g., Monthly Status Report (MSR)
- POCs
- Roles and responsibilities
- Prioritization of Contractor activities
- Quality surveillance
- Any initial deliverables
- Additional issues of concern.

PCORI also will discuss the roles and responsibilities of the PL.

**Project Lead's Authority**

Performance of work will be subject to the technical direction of the PCORI Project Lead or other PCORI representative designated in writing. The term “technical direction” includes, without limitation, direction to the Contractor that directs or redirects the labor effort, shifts the work between work areas or locations, fills in details, and otherwise serves to ensure that tasks outlined in the work statement are accomplished satisfactorily.

(a) Technical direction must be within the scope of the specification(s).
(b) Technical direction may be oral or in writing.

The PCORI Project Lead does not have authority to issue technical direction that:

1. Constitutes a change of assignment or additional work outside the specification(s).
2. In any manner causes an increase or decrease in the agreement’s price, or the time required for performance under the agreement.
3. Changes any of the terms, conditions, or specification(s)/work statement of the agreement.
4. Interferes with the Contractor's obligation to perform under the terms and conditions of the agreement.

**Period of Performance**

The period of performance will be two (2) years from the date of award with an option for an additional third year. The projected award date is **December 1, 2017**.

**Type of Agreement**

PCORI expects to award one (1) Contractor for a cost reimbursable agreement for the four primary responsibilities outlined in this RFP. This agreement type provides an estimate of the work required to be performed over the agreement period. The Contractor must be able to perform all activities described in the RFP SOW. PCORI encourages the use of Contract teaming arrangements and/or subcontractors to ensure that project teams have the necessary expertise to accomplish the work.
Proposal Evaluation Criteria

The Basis of Award will be Best Value. A cost reimbursable agreement will be awarded to the Offeror whose proposal, conforming to the RFP, represents the best value to PCORI. When determining Best Value, technical approach and past performance, when combined, are significantly more important than cost or price. Proposals that are unrealistic in terms of technical or schedule commitments, or unrealistically high or low in terms of price/cost, may be deemed to be reflective of an inherent lack of technical competence, or indicative of a failure to comprehend the complexity and risks of the proposed work and may be grounds for rejection of the proposal. Cost/price is not the most important evaluation factor, but its degree of importance will increase commensurably with the degree of equality among different Offerors’ Technical and Past Performance proposals.

PCORI expects to award no more than one (1) agreement as a result of this Request for Proposal for the four primary responsibilities and to enter into separate research agreement(s) with additional funding relating to the pilot predictive analytics research project(s).

An evaluation of the Offerors’ price proposals will be made to determine if they are realistic for the work to be performed, reflect a clear understanding of the requirements, and are consistent with various elements of the technical proposal. PCORI will evaluate the reasonableness of the price of each compliant offer in relation to the Offeror’s relative quality. Reasonableness will be determined considering other competitive prices received and comparison to the Independent Cost Estimate (ICE).

Whether a price is too high or too low may be considered in the context of comparison to other price proposals as well as to the ICE, or to any other information the Procurement Office deems useful in their discretion. The price reasonableness evaluation will result in a fair and reasonable determination by PCORI.

Proposals will be evaluated using the following criteria:

<table>
<thead>
<tr>
<th>Category</th>
<th>Weight of Rating Factor</th>
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<tbody>
<tr>
<td>Technical Approach</td>
<td>40%</td>
</tr>
<tr>
<td>Project Management Plan</td>
<td>30%</td>
</tr>
<tr>
<td>Past Performance/Experience</td>
<td>30%</td>
</tr>
</tbody>
</table>

PCORI expects that an award will be made to the Offeror who proposes the best value, with the technical approach being most important. PCORI will consider the evaluation factors indicated below.
Technical Approach

Submit a narrative that demonstrates the Offeror’s technical understanding of the requirements and the overall capability and experience in providing the requirements specific to meet the needs of PCORI. Offerors must provide a detailed plan that includes a description of the proposed approach and a detailed draft project plan outlining the requirements in the Statement of Work. Describe which events/activities are envisioned and which contacts and resources are proposed to accomplish the tasks, and demonstrate how the proposed approach will accomplish the objectives specified. This narrative should demonstrate an adequate understanding of the methods underlying predictive analytics and the assessment of heterogeneity of treatment effects, including when this type of analysis is most informative versus when caution is warranted. The Offeror will provide one specific example of an assessment of heterogeneity of treatment effect through the reuse of clinical research data (not data mining) that the Offeror was previously responsible for conducting. The Offeror will describe in detail the process used in that work (including the analytic approach used), reflecting on challenges and lessons learned. If the Offeror has not previously conducted such an analysis, the Offeror should select and submit an exemplar example of the product authored by another researcher, and should explain in detail the reasons for the choice and the strengths of the particular example submitted.

Management Plan

Submit a narrative that addresses the Offeror’s overall capability to manage the work required. Please include an organization chart with named personnel that demonstrates reporting lines and areas of responsibility. A curriculum vitae or NIH biosketch shall be provided in an appendix for each named key personnel and shall demonstrate experience in similar positions on prior projects/contracts that are similar and relevant to the scope and complexity contemplated. Personnel proposed must demonstrate core expertise in the tasks anticipated. If the use of subcontractors is proposed, clearly articulate their roles, and demonstrate their relevant experience. The management plan shall describe the overall plan for organizing, staffing, and managing the tasks; how organization roles and responsibilities will be divided, decisions made, and work monitored; exceptions management; and assurance of quality and timeliness to meet PCORI’s requirements. Please provide a high-level project plan identifying key tasks, milestones, and estimated durations for the tasks as well as an estimate for the total hours required for each labor category.

Past Performance

The Offeror is expected to demonstrate its previous experience in providing the requirements outlined in this RFP. PCORI’s intent is to determine whether the Offeror has performed services on contracts relevant in scope and complexity with the requirements set forth in the Request for Proposal and whether the Offeror consistently delivers quality services in a timely manner. This factor will be evaluated on the basis of the Offerors’ relevant similar experiences during the past three (3) years. The information presented in the Offerors’ proposals, together with information from any other sources
available to PCORI, will be used in the evaluation of past performance. Please see Appendix A for a Past Performance Questionnaire.

All past performance must be for projects which are ongoing or completed within the last three years and all for projects of a similar size, scope, or complexity as the requirements anticipated under this RFP. Please submit three past performance references from the projects identified and provide the following:

- Agreement/contract name
- Agreement/contract description (e.g., identify commodity/service, acquisition methodologies, dollar value of acquisitions supported, type of contract actions, number of resources supporting, performance challenges encountered, corrective actions taken, etc.)
- Dollar amount of contract
- Duration (including start date, completion date, both targeted and actual)
- Point of contact, telephone number, and current e-mail
- Summary of project, including the type of project, the specific topic and scope, and the approach, any challenges, and the final results.

Price Proposal

Offerors are expected to provide Overall Base pricing to support the labor categories in this RFP. Prices will be proposed based on established catalog or market prices. Offerors who are General Services Administration (GSA) Schedule holders are encouraged to offer their currently awarded Schedule prices. There are no intended or implied guarantees regarding PCORI’s award of any agreements issued as a result of the RFP. When evaluating the price proposal, the fully loaded hourly rate of proposed labor categories will be used to evaluate price reasonableness.

The Offeror shall submit functional responsibilities and labor qualifications for each labor category under this RFP. Functional responsibilities shall include the principal duties to be performed by the labor category. Labor qualifications shall include experience and/or education requirements for all labor categories. In addition, the Offeror shall provide a narrative outlining the rationale for the functional responsibilities and qualifications proposed for each category. The proposed labor qualifications will be incorporated into the resulting contract, thereby becoming the standards for use during performance of the effort. In addition to labor costs, non-labor costs shall be provided and any and all indirect fees identified in the proposed budget.

Institutions may apply an approved indirect rate up to 40 percent. The personal salary cap is $200,000 per individual. The cap relates to the annual institution base salary for each person and does not include fringe benefits.
PCORI will assign the following color coding system to evaluate the non-price factors:

<table>
<thead>
<tr>
<th>Color</th>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purple</td>
<td>Exceptional (E)</td>
<td>Exceeds evaluation standards in a beneficial way; has a high probability of satisfying the requirement and has no significant weakness.</td>
</tr>
<tr>
<td>Blue</td>
<td>Good (G)</td>
<td>Meets and sometimes exceeds the evaluation standards and demonstrates a good understanding and ability to meet PCORI’s requirements. There is little risk to PCORI, and the Offeror demonstrates one or more strengths that will benefit PCORI.</td>
</tr>
<tr>
<td>Green</td>
<td>Acceptable (A)</td>
<td>Meets evaluation standards and will satisfy the minimum requirements. Weaknesses are minor and can be readily corrected.</td>
</tr>
<tr>
<td>Yellow</td>
<td>Marginal (M)</td>
<td>Fails to meet one or more evaluation standards. There is a low probability of satisfying the requirements, and the Offeror demonstrates one or more significant weaknesses or has numerous weaknesses.</td>
</tr>
<tr>
<td>Red</td>
<td>Unacceptable (U)</td>
<td>Fails to meet minimum requirements, and noted deficiencies require major revisions to the proposal in order to make the proposal acceptable.</td>
</tr>
</tbody>
</table>

**Award without Communications or Clarifications**

PCORI reserves the right to award without communications or clarifications, so it is in the best interest of each Offeror to include their most favorable terms in their initial submission. However, PCORI reserves the right to conduct communications or clarifications.

**Best and Final Offers**

Subsequent to receiving the original proposals, PCORI reserves the right to notify all technically acceptable Offerors within the competitive range and to provide them an opportunity to submit written best and final offers (BAFOs) for the RFP at the designated date and time. BAFOs shall be subject to the late submissions, late modifications, and late withdrawals of proposals provision of this RFP. After receipt of a BAFO, no discussions shall be reopened unless PCORI determines that it is clearly in PCORI’s best interest to do so (e.g., it is clear that information available at that time is inadequate to reasonably justify Contractor selection and award based on the BAFOs received). If discussions are reopened, PCORI shall issue an additional request for BAFOs to all technically acceptable Offerors still within the competitive range.
Withdrawal or Modification of Proposals

An Offeror may modify or withdraw its proposal upon written, electronic, or facsimile notice if received at the location designated in the solicitation for submission of proposals not later than the closing date and time for receipt of proposals.

Late Submissions

Late proposals, requests for modification, or requests for withdrawal shall not be considered unless a late modification of a successful proposal makes terms more favorable for PCORI.

Retention of Proposals

All proposal documents shall be the property of PCORI, retained by PCORI, and not returned to the Offerors.

Documentation Requirements

The Contractor may be required to provide documentation to support its legal ability to operate facilities in the United States.

Basis of Compensation to the Contractor

PCORI expects to award an agreement for the technical and price proposal that is proposed, negotiated with PCORI during the Best and Final Offer process, and listed in the agreement executed between the organizations. Any Contractor quality issues that result in the re-drafting of work or increased labor required to meet deliverables during the performance of the agreement are the financial responsibility of the Contractor, and re-work will be done at the Contractor’s expense.

Post-Award Debriefing

PCORI’s Procurement Department will provide a timely notification to all unsuccessful Offerors once an award has been made. All unsuccessful Offerors may request a post-award debriefing by providing a written request to RFP@pcori.org within three (3) business days after receiving the award notification. PCORI will provide verbal or written debriefs at PCORI's discretion.
Post-Award Information

PCORI Rights

PCORI will own all documents and materials produced under the agreement that is issued by PCORI to the Contractor under this RFP. Depending on the primary area of responsibility, PCORI will consider granting the Contractor permission to prepare or publish academic papers derived from the work products, potentially with co-authorship with PCORI, subject to Contractor’s obligation not to disclose PCORI confidential information and provided that Contractor does not publish the work products themselves or any part of the work products themselves without PCORI’s advance written consent. To the extent work products are released by PCORI or incorporated into PCORI material, PCORI expects to acknowledge Contractor’s authorship or contributions, as appropriate.

Furnishing of Equipment/Property

The Contractor shall furnish its own office, equipment, personnel, and technology.

Place of Performance

The Contractor is required to provide the facilities necessary to execute the services under the agreement that is issued by PCORI to the Contractor under this RFP. The Contractor shall choose its staff or acquire the necessary personnel support and provide suitable work facilities.

Hours of Service

The Contractor shall be available Monday through Friday, between 9 a.m. and 5 p.m. ET. PCORI has regular observance of federal holidays: New Year’s Day; Birthday of Martin Luther King, Jr.; Washington’s Birthday; Memorial Day; Independence Day; Labor Day; Veterans Day; Thanksgiving Day; and Christmas Day.

Insurance

The Contractor, at its own expense, shall provide and maintain the general liability insurance in support of this contract for the entire duration, including option years, with $1 million minimum coverage. The Contractor assumes absolute responsibility and liability for any and all personal injuries or death and/or property damage or losses suffered due to negligence of the Contractor’s personnel in the performance of the services required under this contract.

Non-Disclosure and Security Requirements

The Contractor, including all of its personnel (to include employees, replacement personnel, subcontractors, teaming partners, and consultants), shall not use or release any sensitive, confidential, or proprietary information without prior written approval from PCORI. The Contractor shall put in place
appropriate procedures for the protection and security of such information and shall be liable to PCORI for any misuse or unauthorized disclosure of such information by its personnel. If requested by PCORI, the Contractor and PCORI will develop an appropriate data security and access plan for providing Contractor with access to certain PCORI Confidential Information.

**Potential for Organizational Conflicts of Interest and Personal Conflicts of Interest**

The term “organizational conflict of interest” means that the Contractor (which term hereinafter shall be deemed to include its chief executives, directors, any employees, or subcontractors utilized under the agreement other than a contractor selling incidental material) has interests in which:

(i) may diminish its capacity to give impartial, technically sound, objective assistance and advise in performing this task;

(ii) may otherwise result in a biased work product under this task; or

(iii) may result in an unfair competitive advantage to itself or others.

The Contractor, including its subcontractor personnel performing work, may receive, have access to or participate in the development of proprietary information (e.g., cost or pricing information, budget information or analyses, specifications or work statements, etc.) which may create a current or subsequent Organizational Conflict of Interests (OCI). The Contractor shall notify the PCORI Procurement Office immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI and shall promptly submit a plan to the Procurement Office to avoid or mitigate any such OCI. The Contractor’s mitigation plan will be determined to be acceptable solely at the discretion of PCORI and in the event that PCORI unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, PCORI may affect other remedies as it deems necessary, including prohibiting the Contractor from participation in subsequent contracted requirements which may be affected by the OCI.

The Contractor, upon award, shall sign a statement confirming that it does not have and will prevent any organizational conflict of interest.

**Compliance**

The Contractor must comply with PCORI’s rules and regulations, all required forms, and any changes in procedures. The Contractor will remain informed of any such changes and updates, as necessary, by the PCORI Procurement Office. Upon the request of employees or other persons with disabilities participating in official business, the Contractor must arrange necessary and reasonable accommodations for the impaired individual(s) per Section 508 Compliance.
**Invoice Content**

The Contractor shall invoice on a monthly basis. The invoice shall include the period of performance covered by the invoice and the level of effort for each task performed. All hours and costs shall be reported by division, task, and labor category, and shall be provided for the current billing month and in total from project inception to date. If teaming or subcontracting is proposed, one consolidated invoice from the prime Contractor shall be submitted in accordance with other terms and conditions of the agreement. The invoice must be signed by an individual authorized by the Contractor. The Contractor shall provide the invoice data in spreadsheet form with the following detailed information (the listing shall include separate columns and totals for the current invoice period and the project to date, identified by division and task):

- Contractor’s name
- Contractor’s address
- Purpose of the invoice
- Date that the invoice was submitted
- Contractor labor category
- Labor rate
- Details of the goods or services provided (for goods, please indicate the quantity) or description of the deliverable
- Travel expenses (if applicable and will need to be provided with receipts)
- Other Direct Costs (ODCs) (if applicable and will need to be provided with receipts)
- Monthly and total cumulative hours worked
- Total value of the invoice.

The Contractor must submit the final invoice within 30 days after the completion of the agreement. The final invoice must be marked “FINAL” and shall be submitted to PCORI. The Contractor agrees and understands that an incomplete invoice will be rejected and returned without payment.

**Billing and Payment Procedures**

PCORI prefers electronic invoicing. Invoices shall be provided to the Finance Department on a monthly basis.

Billing address:

PCORI  
Attn: Finance Department  
1828 L St., NW, Suite 900  
Washington, DC 20036  
E-mail: finance@pcori.org
**Submission Guidelines**

Submissions should be organized in three separate volumes (i.e., two volumes for the Administrative and Technical Proposal and one volume for the Pricing Proposal). All text should be Arial or Times New Roman font, no less than 11 point, with one-inch margins and single spaced. Graphics and tables may be included. We accept MS Word, MS Excel, and Adobe PDF formats.

The Offeror is advised that its offer, if accepted by PCORI, will form the basis of a binding agreement. Therefore, care must be taken to properly address the requirements set forth in the RFP. These instructions set forth requirements for preparation and submission of proposals and to establish format and specific content of each offer. This is to assure completeness and suitability for both evaluation purposes and the cohesiveness of the resulting agreement. Be sure that the proposal explains how your firm will fully satisfy all of the performance requirements of the intended agreement. Submit a complete proposal. Proposals that are not complete may be determined unresponsive and rejected.

Proposals should be sent electronically to rfp@pcori.org. Proposals not received by the time stated above will not be considered.

Questions must be submitted to rfp@pcori.org, referencing **RFP # PCO-PARC 2017** in the subject line: **Predictive Analytics Resource Center** no later than **5:00 p.m. (ET) on September 29, 2017**.

Offerors shall submit proposals in response to this solicitation electronically as follows:

**Volume 1: Administrative – Page Limit: None**

Each submission must include a cover letter with the following information:

- Offeror’s name and mailing address
- Reference to the solicitation (RFP) number (PCO-PARC 2017)
- Technical points of contact (name, phone number, and e-mail address)
- Business size (large, small, state/federal certifications—MBE, 8(a), HUB Zone, etc.)
- Dunn & Bradstreet Number (DUNS)
- Federal Tax ID (EIN, TIN, SS)
- Affirmation that the proposal is valid for at least 30 days
- A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item
- Acknowledgement of any amendments by reference.

1. **Technical Approach** – Page limit: 10 (The submitted example of an assessment of heterogeneity of treatment effect (HTE) through the reuse of clinical research data does not count towards this limit, but it can be labelled as an Appendix to the Technical Approach.)

2. **Management Plan** – Page limit: 5

3. **Past Performance/Experience** – Page limit: 5

4. **Appendices** – No page limit; do not include non-specified other material.
   a) Example of assessment of HTE through the reuse of clinical research data produced by the Offeror.
   b) Resumes/biosketches of key personnel.


The written price proposal for the RFP shall contain the following:

1. Offerors will demonstrate how they arrived at their proposed pricing by detailing labor categories, labor rates, and travel costs.

2. Proposed pricing must include estimated direct expenses including all subcontractor labor (if applicable), travel costs, and other direct expenses. Include burden as applicable, specifying burden rates and burden calculations.

Institutions may apply an approved indirect rate up to 40 percent. The personal salary cap is $200,000 per individual. The cap relates to the annual institution base salary for each person and does not include fringe.

**Cost Reimbursable Agreement**

Material, Other Direct Costs, and Travel will be reimbursed at cost (not additional fee). Offerors shall propose indirect rates applicable to Material, ODCs, and Travel. Indirect rates applicable to Material, ODCs, and Travel are also reimbursed at cost and shall be incorporated into any resultant agreement. No profit/fee shall be proposed. Proposed pricing must include estimated direct expenses including all subcontractor labor (if applicable), travel costs, and other direct expenses. Include burden as applicable, specifying burden rates and burden calculations.

- Any and all indirect rates must be fully supported with applicable documentation. The Offeror shall identify the basis for the proposed indirect rates applicable to Material, Other Direct Costs, and travel (i.e., Forward Pricing Rate Agreement (FPRA), Negotiated Indirect Cost Rate Agreement (NICRA) Forward Pricing Rate Proposal submission, Approved Provisional Billing Rates, budgetary rates, etc.) and provide documentation supporting their proposed indirect rates. These documents are subject to verification and audit.
The Offerors shall provide their current (within the last twelve months) Forward Pricing Rate Agreement or Forward Pricing Rate Proposal submission for indirect rates, and/or Provisional Billing Rates approval letter for current-year indirect rates.
Appendix A: Past Performance Questionnaire

SECTION 1: AGREEMENT IDENTIFICATION

A. Contractor: ________________________________  
B. Agreement Number: ______________________  
C. Contract Type: ____________________________  
D. Period of Performance: _____________________  
E. Current/Final cost: _________________________  
F. Description of services provided:

____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________

SECTION 2: CUSTOMER IDENTIFICATION

A. Customer Name: ____________________________  
B. Description of services under this agreement, i.e., local, nationwide, or worldwide:

____________________________________________________________________________

SECTION 3: REFERENCE IDENTIFICATION

A. Reference’s Name: ____________________________  
B. Reference’s Title: ____________________________  
C. Reference’s Phone/Fax Number: _________________________  
D. Reference’s E-mail Address: ____________________________
SECTION 4: EVALUATION

The purpose of this evaluation is to understand your satisfaction with the Contractor in respect to the delivery of acquisition and administrative support services.

Please indicate your satisfaction with the Contractor’s performance by placing an “X” in the appropriate block using the scale provided to the right of each question. This scale is defined as follows:

<table>
<thead>
<tr>
<th>Scale</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Excellent (E)</strong></td>
<td>Performance meets contractual requirements and exceeds <strong>many</strong> (requirements) to the customer’s benefit. The contractual performance of the element being assessed was accomplished with few minor problems for which corrective actions taken by the Contractor were highly effective.</td>
</tr>
<tr>
<td><strong>Good (G)</strong></td>
<td>Performance meets contractual requirements and exceeds <strong>some</strong> (requirements) to the customer’s benefit. The contractual performance of the element being assessed was accomplished with some minor problems for which corrective actions taken by the Contractor were highly effective.</td>
</tr>
<tr>
<td><strong>Acceptable (A)</strong></td>
<td>Performance meets contractual requirements. The contractual performance of the element being assessed contains some minor problems for which corrective actions taken by the Contractor appear, or were, satisfactory.</td>
</tr>
<tr>
<td><strong>Marginal (M)</strong></td>
<td>Performance does not meet contractual requirements. The contractual performance of the element being assessed reflects a serious problem for which the Contractor has not yet identified corrective actions, or the Contractor’s proposed actions appear only marginally effective or were not fully implemented.</td>
</tr>
<tr>
<td><strong>Unacceptable (U)</strong></td>
<td>Performance does not meet most contractual requirements and recovery is not likely in a timely manner. The contractual performance of the element being assessed contains serious problem(s) for which the Contractor’s corrective actions appear, or were, ineffective.</td>
</tr>
<tr>
<td><strong>Not Applicable (NA)</strong></td>
<td>Unable to provide a score.</td>
</tr>
<tr>
<td>Performance</td>
<td>E</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
<td>---</td>
</tr>
<tr>
<td><strong>Acquisition Management Support Past Performance (as applicable):</strong></td>
<td></td>
</tr>
<tr>
<td>Technical adequacy/effectiveness of quality control programs and adherence to the agreement’s quality assurance requirements</td>
<td></td>
</tr>
<tr>
<td>Effectiveness of overall management (including ability to effectively lead, manage, and control the program)</td>
<td></td>
</tr>
<tr>
<td>Contractor was reasonable and cooperative in dealing with your staff (including the ability to successfully resolve disagreements/disputes)</td>
<td></td>
</tr>
<tr>
<td>Timeliness/effectiveness of problem resolution without extensive customer guidance</td>
<td></td>
</tr>
<tr>
<td>Understanding the customer’s objectives and technical requirements</td>
<td></td>
</tr>
<tr>
<td>Contractor proposed alternative methods/processes that reduced cost, improved maintainability or other factors that benefited the customer</td>
<td></td>
</tr>
<tr>
<td>Contractor implemented responsive/flexible processes to improve quality and timeliness of support</td>
<td></td>
</tr>
<tr>
<td>Ability to hire/apply a qualified workforce to this effort</td>
<td></td>
</tr>
<tr>
<td>Ability to manage transition from prior agreement/service provider</td>
<td></td>
</tr>
<tr>
<td>Rate the firm’s ability to deliver quality service in a timely manner</td>
<td></td>
</tr>
<tr>
<td>Rate the firm’s ability to meet the agreement’s requirements</td>
<td></td>
</tr>
<tr>
<td>Rate the firm’s adherence to project schedules including administrative aspects of performance</td>
<td></td>
</tr>
<tr>
<td>Were you satisfied with the company's performance?</td>
<td></td>
</tr>
<tr>
<td>Would you use them again?</td>
<td></td>
</tr>
</tbody>
</table>

*Please discuss each response for which you indicated Excellent, Good, Marginal, or Unacceptable below:*
NARRATIVE SUMMARY:

__________________________________________________________________________________

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Reference’s Signature               Date

THANK YOU FOR YOUR PROMPT RESPONSE AND ASSISTANCE! Please return this completed questionnaire no later than **October 27, 2017, 2:00 p.m. (Eastern Time)** to:

RFP@pcori.org

Subject: Predictive Analytics Resource Center (PARC) Past Performance