

Proposed Review Criteria for Applications for EHR Data Collection Center

All applications will be scored based upon the following criteria by a review committee of PETAL Investigators and experts in this area.

Reviewers will assign a score to each criteria for all applications received. The score will range from 1 to 6 as below:

Score	Descriptor	Guidance on Strengths/Weakness
1	Excellent to Outstanding	Extremely strong with negligible to minor weakness
2	Very Good	Strong but numerous minor concerns or weakness
3	Good	Strong but at least one moderate weakness
4	Satisfactory	Some strengths but also some moderate weakness or numerous minor weakness
5	Fair	Some strengths but at least one major weakness
6	Poor	Very few strengths and numerous major weakness

The criteria by which the applications will be scores are:

Criterion	Description
Prior Experience	The applicant should demonstrate experience and expertise with abstracting EHR data from multiple hospitals and multiple EHR vendors, ability to validate data, to work with researchers on EHR data, to deliver data for utilization in a timely fashion, and ability to launch sites for EHR data abstraction in a rapid fashion. Were specific examples of past projects included in the application? Are those experience similar to what is needed in COROLLA and asked for in the RFP? What is their past experience with obtaining data use agreements and managing HIPAA/privacy regularions with multiple hospital for the proposed work? How quickly were they able to do so?
Applicant/Organization	In reviewing the organization, key personnel, and infrastructure, is the organization well qualified to perform the requested scope of work? Is there evidence of organization stability (ie: little likelihood that the applicant will go bankrupt within a year or that a key personnel may leave their institution which may jeopardize their ability to deliver the scope of work in a timely fashion)? Is this type of work the primary focus of the applicants/organization or does this represent a new direction/expansion from the primary job/operation for the group? Do the current staffing and structure within the Applicant Organization seem appropriate to do the proposed job? Do most of the staff needed for the job still need to be hired which may compromise ability to deliver in a timely fashion?

Approach	<p>What are the strengths of the proposed approach to data abstraction, validation, clean up, merger, and transmission of data? Are there any minor, moderate or major concerns? Is there a plan for data security to ensure compliance with privacy regulations? Is there an approach to evaluate missing data (i.e. truly missing or just error in abstracting, etc)? How flexible will they be in changing the type of data and what data needs to be abstracted based upon study needs? Do they have the capacity to easily include other data not currently proposed in COROLLA without additional resources or efforts? What is their plan for random sampling of patients for the long term follow-up study? How will they communicate these patients to each site to allow the coordinators to consent them?</p>
Support and requirements of individual COROLLA sites and the CCC	<p>What is their plan with regards to communication, data transmission, collaboration with the CCC? How frequently will they transmit data to the CCC? What is their plan for data validation, clean up, merger of data from multiple sites and transformation as per specification developed by the CCC?</p> <p>What is their plan for what is required to be done at each local COROLLA site in order to get the EHR data to them? What effort and equipment (ie servers or other resources) are required by the local site? What is needed, if any at all, from personnel at the local site to validate the data, to funnel the data to the applicant for their proposed work? How much support will be provided to the local COROLLA site IT staff? How much work will be required to be done at the local site? If work is required at the local site, is there a plan to test the validity and fidelity of what is done at each site to ensure that the same data is collected at every site and that this data is in accordance with the CCC requirements?</p>
Sustainability	<p>How likely will this be transferable to additional trials, future networks, other additional research studies within and beyond PETAL? What is their plan for sustainability beyond COROLLA that may make them future partners in other research activity? Will the infrastructure developed to collect data for COROLLA facilitate future research (1) in collaboration with the Organization, (2) future research through PETAL or a similar network with or without the involvement of the Organization, or (3) future research at each of the local sites independently of the network or the Organization?</p>

Budget: In addition to the above criteria for review and scoring, each reviewer should also assess the budget for appropriateness, value, feasibility.

An itemized detailed budget and budget justification is requested.

The detailed budget should include personnel and what they would be doing, any equipment required of local sites and by applicant, consultant fees, and other services. If the applicant have available other funds that can support this proposal, the applicant can state in the budget justification that the requested budget will be supplemented by external funding and the amount, source and timing of the external funds that can provide additional resources for the project. Reviewers will be able to comment on the budget with regards to appropriateness and size.