RFP for EHR Data Collection Center
Application FAQs

August 27, 2018

Q: *"Estimation of staffing and equipment requirements for each site that will contribute data"* - Can you clarify what information the committee seeks for this question? Would you like us to estimate the resources that will be needed at each of the 24 trial sites?
A: If your proposal requires specific resources at the sites, please include a description of what they would be (i.e., equipment, staff effort, etc.).

Q: Does the 5-page limit include budget justification and personnel listing?
A: No

Q: Should we include investigator biosketches?
A: Yes

Q: May we add a separate facilities and resources page (standard NIH format) outside of the 5-page limit?
A: Yes

Q: Should we budget for a 2- or 3-year project period?
A: Budget should be for 2-year project, staffing can be approximate and listed as FTEs.

Q: What is the funding period?
A: We envision the data collection center contract beginning in about January 2019, with enrollment to begin in the trial during the second half of 2019.

Q: What happens if a needed data element is not available at a given hospital?
A: Part of the criteria for selecting hospitals for the trial will be the ability to consistently deliver the key data points. Some data points, however, will be truly missing. These can be reported as missing in the data from the data collection center. PETAL statisticians and investigators will develop a missing data plan (probably multiple imputation for some variables and reported as missing for others).

Q: Is the COROLLA protocol or protocol synopsis available?
A: Protocol summary document has been added to the RFP documents

Q: Is there a provisional list of hospitals that may participate in the trial?
A: The study proposal is for each Clinical Center to identify 2 of their sites (hospitals) to participate. The total number of hospitals for the network will be 24.

Q: How are subjects enrolled in the study: manual screening and consent? auto-enrollment by identification in EHR?
A: The study will be a cluster-randomized design: SpO2 target (low vs intermediate vs high) will be assigned using a cluster-randomized, multiple-crossover design. All participating EDs and ICUs within a study hospital will serve as a unit (cluster); all mechanically ventilated adults in a unit will be assigned to the same SpO2 target at the same time. The SpO2 target will change for each unit at the end of each study period.

Q: Will any data be collected manually?
A: Yes, there will be some manual data collection for the subgroup of patients randomized to the cognitive outcome assessment group.

Q: May we add indirect costs to the budget?
A: Yes

Q: Who would we be working with within the organization to accomplish this project?
A: The contracted awardee will work with the PI of each site and IT resources/team at their site. We know that the institutional person who can facilitate the EMR data abstraction can differ by institution (IT, research informatics, CTSA or other research group). Each site investigator is supposed to connect the awardee to whoever is best equipped to work the awardee to extract the data. If there is resources/efforts needed from this local personnel, it is important that the applicant state in the application what is expected to be delivered by the local site on their end, what support the applicant will provide to the local site in order to do this, and what resources and efforts should be allotted to each site to ensure their ability to deliver in this effort. In a separate budget from this RFP, the CCC will allot some modest support to each site to allow them to work with the awardee to extract and export data but the amount of support will depend on what the applicant to this RFP propose in their approach with each site. This will be evaluated as part of the application.

Q: What is their relationship with the organization's IT and compliance team?
A: There are over 45 hospitals in the PETAL Network. The COROLLA trial and this RFP will apply to approximately 24 of these sites to ensure that sites with the most experience with EMR data abstraction will be selected for this trial. As such, it is expected that the participating sites will have deep interest and prior experience in abstracting EMR data for research. However, it is still expected that not all of these sites will have prior experience is exporting EMR data for multicenter data aggregation and that even for experienced sites, their approaches differ from each other and from what might be proposed by the applicant. Therefore, it is important that each applicant makes it clear in their description of their approach what they need at each site, what is expected to be delivered from each site internally, how they will support the local investigator and site in terms of their approach, and their prior experience in getting hospitals to export data out.

Q: Are the IT and compliance officers be aware of this project and did they play a role in its design?
A: Local IT and compliance officers did not play a role in the trial design and many are aware of this effort as we had done a prior survey in which many sites reached out to their local IT officers about EMR data abstraction at their site.

Q: Is the EHR frequency list for the participating institutions available?
A: We are estimating that this will be about 24 hospitals. However, if there are sites that share the same EMR system or infrastructure as other participating sites, we may also include them even beyond the estimated 24 sites, if our budget allows

Q: How firm is the 24 site enrollment number?
A: Relatively firm

Q: If there is a fixed desired number of sites: Would PETAL consider a multi-vendor solution or a multi-medium solution (some sites on paper/REDCAP)? If so would the DCC be responsible for setting alternative submission mechanisms (ie paper/REDCAP)?
A: We prefer one vendor for the entire project with one approach for all of the participating sites. It is planned that all data available in the EMR will be exported via the successful awardee to this RFP. However, there will be additional data on a subset of patients that will be recruited to participate in interviews with research coordinators at each site. Those data will be entered manually by the coordinators via a mechanism set up by the DCC.

Q: How many sites need to be live prior to trial starting to recruit first patient? Would recruitment start at only sites in which data extraction is live?
A: Yes we will start recruitment at each site once their data collection becomes live.

Q: What is the projected sample size for this study?
A: About 25,000

Q: How firm is the H2 2019 Trial start date?
A: From a timeline standpoint, this is firm. If we don't start by Jan 2020, we aren't going to get a 12-month trial completed

Q: If trade off's need to be made regarding enrollment start time vs number of centers enrolling, what is to be favored?
A: Both will be important. The trial and all sites must complete the trial to allow for analysis and publication before the end of the funding period in 2021

Q: What information should be available to the participating site regarding the course and conduct of the trial? Will real time feedback (within hours) be needed?
A: As specified in the RFP, there needs to be a mechanism for communicating to each site a random subsample of patients to consent for long term follow up. Ideally, this should be done as close to real time as possible, within days or sooner. In addition, it would be considered an advantage if the sites can get data on compliance to oxygen targets for their participating ICUs in near real time (within 1 day) so that sites can use these data to improve their adherence to the treatment arm. This would not require real time feedback of all data but anonymous feedback on a subset of data (SpO2 and corresponding FiO2 and location in the hospital, for example). Applicants are encouraged to describe their ability to deliver this type of feedback to sites.

Q: Will there be an opportunity to present this proposal and answer questions from the review committee?
A: No, unfortunately it is not possible to allow for this.

Q: How will the final statement of work be agreed upon after the RFP process?
A: After the RFP process and the selection of successful applicant, there will be regular calls to work on the work but we anticipate the final scope of work to be similar to what is described in

the RFP. Any significant alteration and changes can be discussed. If the approach proposed by the applicant is amendable to changes or expansion, we encourage the applicate to describe this in their approach for evaluation.

Q: What will any award of funds be made contingent on?
A: Payment will mimic that of an academic vendor and will reflect the scope of work. Payment will not be contingent on deliverables.

Q: Is there a named contact at the CCC who will review data quality alongside the DCC?
A: Yes, Yes, Dr. David Schoenfeld and other individuals at the Clinical Coordinating Center, Data Coordinating Center and the COROLLA Protocol Committee.

Q: Is there a named person in trial leadership who will review and the outcome measures developed from the extracted data alongside the DCC?
A: Yes, Dr. David Schoenfeld and other individuals at the Clinical Coordinating Center, Data Coordinating Center and the COROLLA protocol committee

Q: What is the existing data collection system at the CCC and is there an expectation of interface with this
A: Currently the CCC uses redcap or external vendors for their data collection system. There is no expectation of an interface with these systems but there is an expectation that the data will be validated and sent to the CCC in a format requested by the CCC that will allow them to merge the EMR data with data collected in the course of the trial through other mechanisms.

Q: Are there required operational metrics which should be apparent to the CCC or at each study site for study progress?
A: Yes. Some examples are number of patients enrolled at each site per week, Adherence rate to study arm by site, compliance and outcomes of enrolled patients (i.e. when off the vent, when out of the ICU, when out of the hospital)

Q: Will the EHR data collection center need to establish new data use agreements with each of the 24 participating COROLLA hospitals?Or will the EHR data collection center be able to leverage ("piggy-back") upon existing data use agreements?
A: The data transfer piece will be managed through the contracts between MGH and the lead institutions with pass through language to cover the subsites. My understanding is that separate DUAs would not be needed in that case.