INFR7: CIRM Patient Support Program Services

Applicant FAQ

Revised 10/05/23

Q. Does the grant award fund the personnel required to administer the program?

A. Yes, the $2.5 M budget can be used for personnel, project oversight and overall program operations.

Q. Does the award cover the direct administrative or transaction costs associated with the reimbursement process (bank fees, etc.)?

A. If these costs are directly attributable to supporting the patient, then they would likely be covered by the Patient Assistance Fund (currently $15.6M). The Patient Assistance Fund is the dedicated fund used to pay for patient costs. A fundamental aim of this award is to administer this fund.

Q. Does the applicant organization need to be headquartered in California?

A. No, the applicant organization must have operations in California to support the PSP. Operations may include personnel or facilities. The program leads should reside in California as they will need to engage clinical trial sites.

Q. How are California operations determined?

A. CIRM expects the management and oversight to be performed by employees paid in California. In addition, in order to ensure that the majority of activities occur in CA, the operational systems, business rules documents, standard operating procedures, operational project flows, educational materials, metric reports and knowledge sharing shall be developed and managed by employees paid in California. It is also expected that the Grantee's California management shall develop relationships with the CIRM team and the California clinical trial sites.

Q. Do support services ("Award Start") need to be available to patients within 120 of days of award approval?

A. No, the 120 days requirement is to initiate work on the approved project plan.

Q. How many patients required patient support services are anticipated per year?

A. CIRM clinical trials enrolled approximately 200 patients over the past year. Treatment sites report 30% - 50% of patients require support services. Annual enrollment numbers have tended to increase annually with an increasing number of active clinical trials.

CIRM does not have a projection of patient numbers as the proportion of patients that would be eligible for support services will vary based on the clinical trial design. However, applicants may use the following information as a basis for estimating new clinical trials over the INFR7 project period. The fiscal year 23-24 CIRM annual research budget projects funding 14 new clinical trials (6 phase I and 8 phase II). Our existing enrolling clinical trial programs (note projected enrollment included in table) combined with newly funded trials may be a way to estimate patient demand for support services.

Q. What patient "navigation" services are required under this application?

A. The call center will direct ("navigate") patient to CIRM-funded clinical trial sites. Screening, eligibility determinations and enrollment will occur at the trial site.

Q. Can applicants propose varied and customized operational call center models for the required activity of providing live support for inbound service requests during normal program hours?

A. The intent of the required activity of live support is to ensure that patient support is provided in a timely manner by qualified PSP staff. The applicants may propose call center models that are well reasoned and are responsive to this stated intent.

Q. Does the award support community engagement programs (personnel and materials)?

A. This award in not specifically intended to support community outreach and engagement. These activities are contemplated in other CIRM programs that would potentially "point" patients to the Patient Support Program. In addition, our Clinical Trial awards include patient engagement efforts.

Q. How will patients requiring patient support services be identified?

A. It is anticipated that in most instances the California trial site (e.g. CIRM Alpha Clinic) will identify enrolled California patients requiring support services and/or evaluation of financial eligibility. Identification of enrolled California patient by the sites will serve to authorize the PSP provider to then determine eligibility and offer support services to the patient.

Q. How will patients requiring patient support services be consented into clinical trials?

A. The clinical trial sites will consent patients and refer them to the PSP administrator.

Q: Can eligible patient costs be paid directly by the PSP provider?

A: Yes.

Q. Is there flexibility in annual project costs?

A. Yes, you may propose an annual budget in excess of $500,000 provided the five-year project costs do not exceed $2.5 million.

Q. Is URAC the only acceptable best practices certification?

A. No, the provider should document any relevant evidence of certification by an organization such as the URAC, International Standards Organization, American Health Information Management Association, the American Medical Association, or the American Academy of Professional Coders in ICD-10 training and Clinical Documentation Improvement or other appropriate body or standard.