FAQ Alpha Clinics Network Expansion Award INFRA4 2022

This document includes questions regarding the Alpha Clinics Network Expansion Award and CIRM's response. The FAQ will be periodically updated in response to ongoing questions received by CIRM.

Questions relating to lead offerings:

Q. Must lead offerings be immediately ready for distribution across the network?

A: Lead offerings should leverage expertise and resources at your center and be made available to network partners in a timely manner. Award funds may be used to support the distribution of this capacity across the network, further develop these resources, or bring in new resources with the goal of meeting unmet needs for clinical research, increasing the ability to efficiently support a growing number of regenerative medicine clinical trials, or present an opportunity for innovative approaches to clinical research and the delivery of these treatments to the patient community. You should provide a timeline for the roll out of your lead offerings.

Q. Must these be fully formed – can one or more be under development?

A: Lead offerings should leverage the expertise and resources at your center, and the offerings should add value to regenerative medicine research in the near term. Consistent with the response above, you may propose reasonable lead time to support the scaling, distribution, or subsequent development of this capacity. We recognize many processes, protocols and research methodologies undergo continuous improvement or development. Your proposed offerings should have the potential to add value to regenerative medicine research in the near term, and award funds may be used to support ongoing development.

Q. Are funds from the Expansion Award to be used to provide lead offering services to others?

A: As noted above, award funds may be used to support the ongoing development or distribution of a lead offering. If the applicant is proposing to provide a service, such services may be provided to network partners or other organizations on a fee-for-service basis and/or included in the budgets of other CIRM awards. Applicants are encouraged to describe how services will become integral to clinical operations, so they are available beyond the award period.

Q. We are also unclear as to whether "lead offerings" refers specifically to clinical therapies in the pipeline or core infrastructure capabilities? Is this referring to sharing of information in order to replicate trials at other network sites?

A: A lead offering is a core infrastructure capability. A lead offering could include information necessary to replicate trials at other sites, but if you look at the examples under "Advanced Regenerative Medicine Research Platforms" in the RFA, notice they include specialized knowledge and operational capacities. You should have a plan for making this capability available to other network partners. Also, these capabilities and/or services can be offered via collaborative agreements or on a fee-for-service basis so they can become integral to your clinical operations. In this sense, they are like the existing clinical research capacity you already provide to sponsors, but they are specifically focused on advancing the regenerative medicine in a networked environment.

For the sake of example, let's assume the offering is a highly specialized clinical delivery system unique to your site. In this example, you could propose a plan to make that resource accessible to other network sites, describe how you could bring value with this collective experience and knowledge and describe data sharing and publication plans that would inform the community of the value of this resource.

Questions relating to knowledge sharing:

Q: **Please provide some clarification on the following aspect of the Knowledge Sharing Plan component of the application: *Applicants should develop plans intended to capture operational information vital to evaluating or replicating the (1) clinic's core competencies, (2) training programs, and (3) lead offerings.* Please expand on what is meant by "*evaluating or replicating*" training programs and lead offerings?**

A: Knowledge (data) sharing plans are a requirement of all CIRM awards and is described in CIRM's strategic plan. In the context of your training program, the evaluation could include coursework and training material, proposed core competencies, metrics such as the number of individuals trained, whether they received a credential (if applicable) and the roles and responsibilities trainees are now filling in the field. For example, MD fellowship programs typically propose to train a certain number of candidates, require completion of a curriculum, and track subsequent candidate placement and publications. You are expected to propose a plan for deploying DEI principles in this training program so you will be asked to propose a recruitment and follow up plan that enables you to track relevant metrics as well as outcomes—e.g. highest degree earned, position attained after completing their training and participation in the Alpha Clinics rotation. In this example, knowledge sharing would enable an outside observer

to understand (1) how well the program performs and (2) what would be required to replicate it.

Questions relating to training programs:

Q. **We are unclear as to whether "training programs" refers to training of Alpha Clinic staff (e.g., clinical coordinators, regulatory coordinators, pharmacy) or regenerative medicine trainees such as residents and fellows? Is CIRM interested in creating access to staff education modules between network sites?**

A. The Regenerative Medicine "training program" may include clinical coordinators, regulatory coordinators, pharmacy, scientists or clinical residents or fellows. Fundamentally, the program should offer a defined curriculum aimed at providing the training candidate with specialized knowledge and skills to support the development or delivery of regenerative medicine treatments. The RFA asks to "consider how training and education opportunities could be extended". If you contemplate a curriculum that could be shared or serve to enroll trainees from other organizations, such an arrangement would be consistent with overall aims of this program, but access to modules is not a requirement. Also describe whether there is any interest or potential for your program to work within the network and professional societies to develop certification programs.

Q. **How does the training program in this RFA relate to other CIRM training programs we may be involved in such as Bridges COMPASS?**

A. Funds from this award should be specifically targeted towards training needs for **clinical research**. As suggested in the RFA, these needs include MDs, nurses, research coordinators, patient navigators, cell pharmacists among others. Other CIRM training programs tend to focus on earlier stage research. We imagine that interactions between trainees at different levels can be beneficial, so you are welcome to propose interactions between trainees or programs as a means of enhancing your overall education programs.

General questions:

Q. **Regarding the item below on page 14 of the RFA: "Describe how the proposed clinic will work with sponsors to facilitate clinical trial agreements/contracts and required assurances," Is there anything specific that you are looking for regarding this question, such as the processes implemented at the institution to create agreements, or do you prefer a more general perspective?**

A: Consider describing key touch points in your established systems for bringing sponsors to your site and initiating trials, and anything special you do or offer for cell and gene therapy. For example, clinical trial success can benefit from systems or processes that:

- Can connect sponsors to PIs at your center in a timely manner
- Provide robust coverage analysis to understand payments
- Ensure IRBs are appropriately constituted to review cell and gene therapy protocols
- Facilities are appropriately licensed to process or manage therapeutic products

These are fairly standard processes, so I imagine your systems are already quite mature? To the extent you have unique capacities specific to cell and gene therapies baked in, then that is worth noting. Also, you might discuss your ability to participate in IRB Reliance agreements or work with central IRBs as there may be protocols where either of these mechanisms are available or required.

Any approaches, systems, or experiences you have in accelerating clinical trial agreements, working with master agreements or other mechanisms for facilitating contracting would be helpful.

Q. **Would it be acceptable if we proposed 2 Co-PDs? Would it be acceptable if one of the Co-PIs is a MD with an active California medical license and the other one a MD/PhD (or PhD) with no active California medical license?**

A. Only one PD or PI is allowed.