



Application #	GWG INFR8-18772
Title (as written by the applicant)	Community Center of Excellence for Regenerative Medicine
Project Objective (as written by the applicant)	Establish a sustainable, community-anchored clinical trial center to expand access to regenerative medicine therapies and develop a skilled workforce for the 750,000+ patients served by County Department of Health Services (DHS) health facilities and disseminate information on regenerative medicine to the community.
Summary (as written by the applicant)	<p>This application proposes to establish a Community Center of Excellence for Regenerative Medicine for increasing access to regenerative medicine clinical trials for the 750,000+ patients served by a Southern California county's DHS medical centers and affiliated clinics who currently have no access to these trials. The overall structure of this proposal begins with infrastructure enhancements, community outreach, and education aimed at increasing referrals to CIRM Alpha Clinics for regenerative medicine trials. Initially, we will offer in vivo gene therapy trials and refer eligible patients to an Alpha Clinic Network site for trials not feasible at the CCCE. Later, we will offer off-the-shelf cell therapies. These efforts will advance CIRM CCCE goals by expanding access to regenerative medicine therapies and strengthening the workforce needed to deliver them to many more Californians.</p> <p>Our CCCE proposes the following objectives:</p> <ol style="list-style-type: none"> 1.Enhancing Clinical Trial Infrastructure and Operations: The current investigational drug pharmacy and clinical research center will be expanded and upgraded to meet regulatory requirements to support in vivo gene and off-the-shelf cell therapies. 2.Clinical Trial Support. The CCCE will enhance clinical infrastructure and skilled workforce, easily accessible to county DHS patients for delivery of in vivo regenerative therapies along with screening and referral to a CIRM Alpha Clinic when appropriate, thereby extending services to a wider geographic area. 3.Patient Access and Patient Support Program: Our navigators and community outreach programs will provide patients education on regenerative medicine therapies, guide them through the clinical trial process, provide transportation assistance, and accompany them to study visits. 4.Workforce and Career Development: Our CCCE will facilitate educational and clinical experiences to advance regenerative medicine knowledge: 1) Provide bidirectional training between community partners and clinical providers; 2) Build awareness of disease-specific patient perspectives; 3) Leverage and expand the existing training programs to incorporate regenerative medicine; and 4) Utilize the CIRM and Alpha Clinic Network education and training programs. 5.Community-based Partnerships and Outreach: The CCCE will strengthen collaboration with our community-based partners and local clinical teams to support community education, outreach, advocacy to increase clinical trial participation. 6.Knowledge Sharing and Evaluation: The MRCT Logic Model will be adapted to include all of the CCCE program components and to seamlessly interdigitate with the Alpha Clinic Network. 7.Organization Integration and Infrastructure Interconnectivity. The CCCE will refer patients to the CIRM Alpha Clinics when clinically indicated trials are not available locally and coordinate with the CIRM Patient Support Program to assist patients in accessing clinical trials.
Statement of Benefit to California (as written by the applicant)	This CCCE will broaden access to regenerative medicine clinical therapies for geographically dispersed, culturally diverse, and underserved communities in the host County. By expanding infrastructure, training healthcare workers, students, and our communities on engaging these populations and regenerative medicine approaches, the project will expand access to trials and provide lasting benefits through improved inclusivity in future research, ultimately advancing health outcomes across California.
Funds Requested	\$9,000,000
GWG Recommendation	Recommended: Exceptional merit and warrants funding, if funds are available
Process Vote	All GWG members unanimously affirmed that "The review was scientifically rigorous, there was sufficient time for all viewpoints to be heard, and the scores reflect the recommendation of the GWG."



	Patient advocate members unanimously affirmed that “The review was carried out in a fair manner and was free from undue bias.”
--	--

SCORING DATA

Final Score: 90

Up to 15 scientific members of the GWG score each application. The final score for an application is the median of the individual member scores. Additional parameters related to the score are shown below.

Mean	90
Median	90
Standard Deviation	2
Highest	92
Lowest	85
Count	15
Tier 1 (85-100): Exceptional merit and warrants funding, if funds are available	15
Tier 2 (1-84): Not recommended for funding	0

KEY QUESTIONS AND COMMENTS

Proposals were evaluated and scored based on the key questions shown below, which are also described in the PA/RFA. Following the panel’s discussion and scoring of the application, the members of the GWG were asked to indicate whether the application addressed the key question and provide brief comments assessing the application in the context of each key question. The responses were provided by multiple reviewers and compiled and edited by CIRM for clarity.

Key Strengths and Weaknesses
<ul style="list-style-type: none"> • The proposed program has the potential to create meaningful and impactful access to experimental and commercial regenerative therapies to a very large population. Strengths include the team, the collaborative model, support, contingency planning, and multi-faceted approach to community engagement. • Strength: Applicant team has appropriate experience conducting clinical trials including physician-scientists and other subject matter experts with expertise in rare disease management, patient care, and community outreach. • Key strengths: Strong plan for multi-institutional collaborations, bi-directional partnerships with and engagement of the affected communities, and well-thought out workforce development / training. The collaborations planned during the course of CIRM-funding of the CCCE could be a model that other Alpha Clinics can leverage for ensuring uninsured patients have access to Alpha Clinic based trials. • Distinct geographic areas that would benefit underserved populations and is thus a strong value proposition. • Thoughtful design and planning for how to deploy this, focusing first on allogeneic therapies which speaks to the plan and design of the proposal. • Impactful value proposition clearly outlined and supported by evidence; deliverables clear as is value proposition. • >750K unique patients at [institution], underscore geographic/functional isolation from existing Alpha Clinics. Participants will be recruited from two major medical centers and 22 ambulatory health center/clinics located that are currently not accessed by the CIRM Alpha Clinic Network; describe diverse patient population, >60% primary language other than English. • Clear evidence of expansion of CIRM'S current Clinical Trial Infrastructure and Operations: The current Investigational Drug Services (IDS) and Clinical & Translational Science Institute (CTSI) supported clinical and translational research center will be expanded and upgraded to meet regulatory requirements to support in vivo gene and off-the-shelf cell therapies. This will be completed by the end of year 1 enabling delivery of therapies on the CCCE campus in years 2-5. • The applicant delineated the # of patients with diseases current trials they plan to engage are targeting and did an medical record snapshot that supports the rationale for starting with sickle cell disease and also is an acceptable # of the proposed rare diseases, and still reaches a new population. • Well described measures, excellent buy in and support by the organizations. • Will reach an underserved population. • Key weakness: A significant portion of patients served through this CCCE both during and by the end of the 5-year period ultimately requires treatment delivery at an Alpha Clinic (for cell-based therapies and



gene therapies requiring stem cell transplant). This includes patients with sickle cell disease, which are the largest population in the community at risk identified in the CCCE application.

- Weaknesses include challenges to engaging this underserved population and ensuring infrastructure is built in a timely fashion.
- Weakness - No plans to expand accessibility of gene therapy beyond what currently exists in the Alpha Clinics geographically near to the proposed CCCE areas.

Value Proposition

- The proposed center is a comprehensive and well-developed proposal that has tremendous potential for the local community, for patients that are geographically and economically isolated, as well as for clinical trial sponsors and other healthcare providers. This Center offers the potential for increased collaboration, education, outreach, and community engagement. The proposed key personnel, network of facilities, facility improvements, and ongoing bi-directional educational activities are designed to offer maximum impact.
- The center is uniquely positioned to expand geographic access to more than 5 million patients across the metropolitan area who are geographically and economically segmented from other care options. The center can provide access to a significant number of patients, across several underrepresented groups, to ensure improved access to regenerative medicine treatments and clinical trials.
- Strength - Participants will be recruited from two major medical centers and 22 ambulatory health center/clinics located that are currently not accessed by the CIRM Alpha Clinic Network.
- Strength - Applicant team provides plans for career development of community health workers and clinical providers at the two safety net hospitals as outlined in their workforce development plan, enabling appropriate after-treatment follow-up from the Alpha Clinics.
- Potential to overcome structural barriers that prevent a large population from access care.
- My major concern is about value added and future significance. I appreciate from the presentation that this subset of patients are currently unable to access Alpha clinics largely due to insurance status and to varying degrees community engagement and transportation, however shouldn't overcoming this barrier be a focus of the Alpha Clinics, the CLIN2 and PSP programs? Especially to ensure sustainability beyond the 5-year program. At the present time, the largest portfolio of cell/gene therapies require autologous *ex vivo* manipulation with cell administration following lymphodepleting or marrow ablating chemotherapy. This CCCE is not being positioned to make such treatments available, rather serving as a funnel to nearby Alpha Clinics. My initial observations combining Table 7.a.2 and Table 9 for patients (in vivo versus *ex vivo* cell/gene therapy) served still holds.
- Value added is good, but some limitation in that the plan is to be geographically close to established Alpha Clinics (existing infrastructure).

Plan and Design

- Strength: The evaluation plan and schedule provided provides necessary operational information, and enables enable effective knowledge sharing; logic model and description of bidirectional partnerships also provided.
- Appropriate consideration has been given to facility improvements, functional collaborations across institutions, and ensuring appropriate medical, scientific, operational, and clinical staffing are available for this collaboration. Clinical operations plans have been developed to expand access and accessibility to regenerative medicine treatments and clinical trials.
- The applicant has an effective plan that considers facility improvements and pharmacy logistics to manage both investigational and approved regenerative medicine products within a reasonable timeframe.
- Appropriate consideration has been given to thoughtful education and professional career development activities through the roles of several key personnel noted within the proposal. In addition to medical, scientific, and clinical training, the inclusion of educational opportunities focused on community engagement, trust-building, and outreach are also present.
- Collaboration with community partners, which is bidirectional.
- Clearly outlined and feasible; scope of value add when it comes to both commercial and investigational products, diseases and research personnel, including rare diseases (prior application mainly focused on SCD, still using as a model initially which makes since given >90% of potential patients from the chart shared have SCD), actual implementation of planned activities, and key personnel list.
- Clear bidirectional partnerships, logic-model driven, opportunities for engagement, training, longevity.
- Clear process for collaborating with Alpha Clinics as well as value add and broadening reach of Alpha Clinic trials; clear processes for inter-connectivity/shared resources.
- The project plan and design for the proposed scope is strong. Excellent collaborations and networks have been established.
- The campus will be upgraded in Year 1 to support advanced gene and cell therapy trials. These upgrades will allow FDA-approved trials to be delivered locally starting in Year 2 and will use existing clinical teams



and add new staff (e.g., pharmacist, research nurse) to manage increased trial volume. Fast-track regulatory processes and contract negotiations will help launch trials more quickly and safely.

- The training and career development strategy is clinicians and clinical fellows, nurses and clinical trial coordinators, trainees ranging from high school through postdoctoral fellows, and navigators and community health workers. Patient navigators will help coordinate logistics like transportation, housing, and meals, especially for trials at the Alpha Clinic that are not available at CCCE.
- Will offer training for clinicians, researchers, students, and community health workers. Programs will include didactic sessions, hands-on training, and shared learning with the Alpha Clinic. Cultural awareness and community input will shape training programs to better serve local populations.
- CCCE will partner with trusted community organizations to reach underserved populations. New programs will focus on educating communities about clinical trials and regenerative therapies, especially in African American and Latino communities. Disease-specific advocacy groups will help train staff and engage families, improving recruitment and retention in trials.
- Applicant will continuously assess and adjust its efforts based on data and feedback. Lessons learned will be shared with the broader CIRM network to improve efficiency. The program will connect with other Alpha Clinics and CIRM-funded researchers to build a strong, integrated regenerative medicine network across the area.
- Well described measures in all components.

Feasibility

- The proposed plan, while ambitious, is realistic, has the appropriate support in place, and pre-identified collaborations to be quickly implemented according to the proposed timeline.
- The applicant, key personnel, and overall proposed team are exceptionally well-qualified across all key areas required for this proposal. The proposed team includes several well-known physician-scientists, as well as appropriate subject matter experts that bring extensive experience in clinical development, rare diseases management, patient care, and community outreach. This team is well-suited and well-qualified.
- The proposed team appears to have the necessary letters of support, endorsements, and backing from the key collaborators that will be central to the successful implementation of this proposal.
- Strength: Applicant team has appropriate experience conducting clinical trials including physician-scientists and other experts with expertise in rare diseases management, patient care, and community outreach.
- Appropriately engaged experts, support, and feasible deliverables; feasible within timeline, not overly ambitious; clear contingency plans for potential hardships; clearly defined institutional support.
- They have thought through each component of the grant.
- Timeline is appropriate.
- Institutional support to help if hardship arises.
- The project is feasible for the scope described.

Serving the Needs of California Patients and Affected Communities

- I absolutely endorse and applaud the mission to ensure that uninsured and ethnically underserved communities in [redacted region] have access to life-saving cell and gene therapies offered through CIRM/other trials or commercially-approved products. For sustainability, CIRM's portfolio of Alpha Clinics, Patient Support Program and CLIN2 programs concentrated in the region should be developed/strengthened to ensure uninsured patients have access. Investment in a CCCE in this area should not be merely a temporary substitution for what should already be an obligation of existing programs.
- Proposing a community-based clinical trial site, coupled with robust education and outreach efforts. Despite geographic proximity to CIRM Alpha Clinics, the communities have been isolated from trial access. They will solve this by:
 - Partnerships with trusted CBOs and disease-specific advocacy groups to foster culturally appropriate outreach.
 - Community Advisory Board (CAB) to ensure transparency, feedback, and accountability.
 - Bi-directional training of community health workers and promotoras to bridge gaps in understanding and trust between researchers and patients.
 - Outreach efforts integrated into local events, faith-based programs, pop-up clinics, and digital platforms to share bilingual, accurate clinical trial information.
- The proposal has significant potential to massively increase education, awareness, trust, and ultimately referrals to clinical trials and approved treatments. The community engagement portion of this proposal is very strong.
- Great consideration has been given to engage with underrepresented populations and to build-out community-based partnerships with organizations tied to specific target groups (ie., Latino, Black, non-English speaking, etc)



- This project team appears to have significant experience engaging patients and affected populations. The proposed pilot program within sickle cell diseases represents an excellent example of utilizing the team's experience and expertise to develop a proof-of-concept model that can then be expanded to other diseases, states, and populations.
- Strength: Propose partnerships with trusted CBOs and disease-specific advocacy groups to foster culturally appropriate outreach; Community Advisory Board to ensure transparency, feedback, and accountability; outreach activities through local events, faith-based programs, and digital platforms.
- Increase access to trials for a largely non-English speaking population in the area.
- Tools developed will enable ultimate goal.



Application #	FWG INFR8-18772
Title (as written by the applicant)	Community Center of Excellence for Regenerative Medicine
Project Objective (as written by the applicant)	Establish a sustainable, community-anchored clinical trial center to expand access to regenerative medicine therapies and develop a skilled workforce for the 750,000+ patients served by County Department of Health Services (DHS) health facilities and disseminate information on regenerative medicine to the community.
Summary (as written by the applicant)	<p>This application proposes to establish a Community Center of Excellence for Regenerative Medicine for increasing access to regenerative medicine clinical trials for the 750,000+ patients served by a Southern California county's DHS medical centers and affiliated clinics who currently have no access to these trials.</p> <p>The overall structure of this proposal begins with infrastructure enhancements, community outreach, and education aimed at increasing referrals to CIRM Alpha Clinics for regenerative medicine trials. Initially, we will offer in vivo gene therapy trials and refer eligible patients to an Alpha Clinic Network site for trials not feasible at the CCCE. Later, we will offer off-the-shelf cell therapies. These efforts will advance CIRM CCCE goals by expanding access to regenerative medicine therapies and strengthening the workforce needed to deliver them to many more Californians.</p> <p>Our CCCE proposes the following objectives:</p> <ol style="list-style-type: none"> 1.Enhancing Clinical Trial Infrastructure and Operations: The current investigational drug pharmacy and clinical research center will be expanded and upgraded to meet regulatory requirements to support in vivo gene and off-the-shelf cell therapies. 2.Clinical Trial Support. The CCCE will enhance clinical infrastructure and skilled workforce, easily accessible to county DHS patients for delivery of in vivo regenerative therapies along with screening and referral to a CIRM Alpha Clinic when appropriate, thereby extending services to a wider geographic area. 3.Patient Access and Patient Support Program: Our navigators and community outreach programs will provide patients education on regenerative medicine therapies, guide them through the clinical trial process, provide transportation assistance, and accompany them to study visits. 4.Workforce and Career Development: Our CCCE will facilitate educational and clinical experiences to advance regenerative medicine knowledge: 1) Provide bidirectional training between community partners and clinical providers; 2) Build awareness of disease-specific patient perspectives; 3) Leverage and expand the existing training programs to incorporate regenerative medicine; and 4) Utilize the CIRM and Alpha Clinic Network education and training programs. 5.Community-based Partnerships and Outreach: The CCCE will strengthen collaboration with our community-based partners and local clinical teams to support community education, outreach, advocacy to increase clinical trial participation. 6.Knowledge Sharing and Evaluation: The MRCT Logic Model will be adapted to include all of the CCCE program components and to seamlessly interdigitate with the Alpha Clinic Network. 7.Organization Integration and Infrastructure Interconnectivity. The CCCE will refer patients to the CIRM Alpha Clinics when clinically indicated trials are not available locally and coordinate with the CIRM Patient Support Program to assist patients in accessing clinical trials.
Statement of Benefit to California (as written by the applicant)	This CCCE will broaden access to regenerative medicine clinical therapies for geographically dispersed, culturally diverse, and underserved communities in the host County. By expanding infrastructure, training healthcare workers, students, and our communities on engaging these populations and regenerative medicine approaches, the project will expand access to trials and provide lasting benefits through improved inclusivity in future research, ultimately advancing health outcomes across California.
Funds Requested	\$9,000,000
FWG Recommendation	Recommended: warrants funding



Process Vote	<p>All FWG members unanimously affirmed that “The review was scientifically rigorous, there was sufficient time for all viewpoints to be heard, and the scores reflect the recommendation of the FWG.”</p> <p>Patient advocate members unanimously affirmed that “The review was carried out in a fair manner and was free from undue bias.”</p>
---------------------	--

SCORING DATA

Final Score: 86

Up to 15 scientific members of the GWG score each application. The final score for an application is the median of the individual member scores. Additional parameters related to the score are shown below.

Mean	87
Median	86
Standard Deviation	3
Highest	90
Lowest	85
Count	7
Tier 1 (85-100): Exceptional merit and warrants funding, if funds are available	7
Tier 2 (1-84): Not recommended for funding	0

KEY QUESTIONS AND COMMENTS

Proposals were evaluated and scored based on the key questions shown below, which are also described in the PA/RFA. Following the panel’s discussion and scoring of the application, the members of the FWG were asked to indicate whether the application addressed the key question and provide brief comments assessing the application in the context of each key question. The responses were provided by multiple reviewers and compiled and edited by CIRM for clarity.

Key Strengths and Weaknesses	
<ul style="list-style-type: none"> • Key strength: The applicant has proposed the development of a pharmacy to support the production of therapies for patients in the nearby clinical research center. The proposed facility is appropriately designed, and the level of architectural and engineering detail demonstrates the project team’s substantial experience in planning and delivering specialized facilities of this type. • Key weakness: While the applicant did a exceptional job of detailing the scope of work for the pharmacy, they did not provide any level of detail nor justification. They actually provided conflicting statements related to scope in the narratives and drawings for requesting funds to refresh the finishes (flooring, paint and ceiling tiles) in three patient exam rooms. The positives related to the pharmacy scope and its impact outweigh the negatives of the finishes upgrade in the clinical research center. • Generally, the scope, design, and schedule were thought out and completed by professionals. The schedule might be slightly aggressive, and a good portion of the scope is set to be completed prior to the award. The applicant should be aware that the expenses made prior to award approval are not reimbursed by the grant. This reviewer felt as though the application was well thought out and professional. • The proposed renovations and designated spaces support the CCCE program needs. • A panelist noted the applications strong clinical success and noted a mixed review of the build out. 	
Appropriateness of the renovation and facilities improvement project to support the proposed CCCE activities	
<ul style="list-style-type: none"> • The level of detail in the proposed design does an exemplary job of demonstrating alignment and appropriateness to support the goals of the clinical research center. • Yes, the scope for the facility improvements seem to align with the CCCE goals. The proposed location and layout accomplish the programmatic goals of the overall application. • This application proposes two distinct but complimentary projects - expansion of pharmacy to support regenerative medicine trials and modernization of three patient rooms. Renovations to the pharmacy should enhance the safety of drug preparation and transport. Patient room renovation is designed to 	



improve patient safety with additional monitoring. Patient room renovation is designed to enhance patient and family comfort and entertainment while therapy is delivered.

- There is great attention to design details, and the application makes a solid effort to identify risks to construction timeline and permitting.

Feasibility of the proposed renovations/facility improvements

- The proposed schedule for the project is very detailed, and the sequenced steps clearly and adequately defined. The only concern is that the project start date is several months before CIRM's anticipated "notice of grant award" announcement date is expected to be made.
- As mentioned above the proposed timeline seems sufficient but contemplates all the needed tasks to complete the facility modifications. Having a facilities manager and an esteemed architecture firm demonstrates that the applicant has appropriate third-party and in-house expertise.
- The timeline seems very compressed, with overlapping phases that seem illogical to one reviewer.

Appropriateness of the renovation/facility improvement costs

- The cost estimates specific to the renovation appear to be fair and reasonable and acknowledge the requirement for prevailing wages. The applicant has committed funding not only for the known scope of work, but they have also committed to cover any additional costs, contingencies, or unforeseen conditions.
- The proposed costs seem appropriate for the scope; however, the applicant did not provide any third-party budget back up from a reputable General Contractor. I assume with the amount of matching funds that the applicant understands the risks of construction costs. The construction costs are minimal compared to the overall grant request. The applicant has acknowledged that the budget and project will adhere to prevailing wages.
- Costs for consultants and subcontractors is low, reflecting using personnel and equipment from prior grants to good effect.



Application #	GWG INFR8-18824
Title (as written by the applicant)	Inland Empire and Desert Region CIRM Community Care Center of Excellence (EIDR CIRM CCCE)
Project Objective (as written by the applicant)	Currently there is no access to the CIRM clinical network in our region. A CIRM CCCE award would establish this space within our geographical area as a centralized, trusted destination for patients seeking cell, gene and regenerative medicine therapy (CGRMT) clinical trials and in Inland Empire and Desert region (IEDR) of California, allowing local delivery.
Summary (as written by the applicant)	<p>The proposed Inland Empire and Desert Region (IEDR) CIRM Community Care Center of Excellence (CCCE) will provide centralized space, dedicated personnel, and pivotal resources that increase access, awareness, recruitment, and availability of cell and gene regenerative medicine therapies (CGRMT) in approved clinical trials.</p> <p>EIDR CIRM CCCE will leverage existing personnel and infrastructure, a FACT accredited program, an information technology research support team, a tele-health program, and various partnerships. EIDR CIRM CCCE will also establish decentralized closed Point-of-Care (POC) Good Manufacturing Practices (GMP) capacity for local production of cell and gene therapy products (in collaboration with a CIRM Alpha Clinic and their GMP) and the capability for intra-cerebral delivery of CGRMT.</p> <p>To make CGRMT broadly available to Californians, EIDR CIRM CCCE will establish a new community-based outreach and engagement (COE) program that promotes awareness and education about CGRMT clinical trials. Various partnerships and plans outlined below will boost access and recruitment to these trials. COE will play a key role in building trust and fostering partnerships by demonstrating transparency, accountability, and inclusivity.</p> <ul style="list-style-type: none"> • We will partner with a second Alpha Clinic and their COE program to implement training, educational interventions, and capacity-building initiatives for diverse communities. • We will capitalize on a local University health system's extensive existing network of hospitals, primary care and specialty clinics, primary care clinics serving an Indian Reservation, federally qualified Health Centers networks, and the Veterans Affairs Healthcare System to expand our access to patient recruitment. <p>Finally, EIDR CIRM CCCE will expand and implement career development curricula and programs in CGRMT and collaborate with Alpha Clinics' educational efforts. In overview, a CIRM CCCE award will establish this facility as a centralized, trusted destination for patients seeking CGRMT in the IEDR of California.</p>
Statement of Benefit to California (as written by the applicant)	<ul style="list-style-type: none"> • EIDR CIRM CCCE will enable operational improvements to accelerate FDA-authorized clinical trials involving CGRMT, allowing local delivery, with specific emphasis on CIRM-funded clinical trials. • EIDR CIRM CCCE will establish capacity for local production of cell and gene therapy products, leading to decreased cost and increased local access. • EIDR CIRM CCCE will facilitate information exchange, provide education, and ensure stakeholders' voices are integrated into decision-making.
Funds Requested	\$9,000,000
GWG Recommendation	Recommended: Exceptional merit and warrants funding, if funds are available
Process Vote	<p>All GWG members unanimously affirmed that "The review was scientifically rigorous, there was sufficient time for all viewpoints to be heard, and the scores reflect the recommendation of the GWG."</p> <p>Patient advocate members unanimously affirmed that "The review was carried out in a fair manner and was free from undue bias."</p>

SCORING DATA

Final Score: 89

Up to 15 scientific members of the GWG score each application. The final score for an application is the median of the individual member scores. Additional parameters related to the score are shown below.



Mean	89
Median	89
Standard Deviation	3
Highest	95
Lowest	83
Count	14
Tier 1 (85-100): Exceptional merit and warrants funding, if funds are available	13
Tier 2 (1-84): Not recommended for funding	1

KEY QUESTIONS AND COMMENTS

Proposals were evaluated and scored based on the key questions shown below, which are also described in the PA/RFA. Following the panel's discussion and scoring of the application, the members of the GWG were asked to indicate whether the application addressed the key question and provide brief comments assessing the application in the context of each key question. The responses were provided by multiple reviewers and compiled and edited by CIRM for clarity.

Key Strengths and Weaknesses
<ul style="list-style-type: none"> • The key strength of this application is that it builds on an already implemented foundation of clinical trial recruitment and execution as well as an excellent community engagement program. It serves a large area with unmet needs and has the potential to bring cell and gene therapy trials to this population. There is also strength in the already existing cell and gene therapy services offered. There is less detail on how the applicant will execute on their point of care manufacturing strategy, but their partnership with an Alpha Clinic should help in this regard. • Strong community outreach plan and community engagement approach. Feedback loop with community groups and disease specific patient advocacy groups. The mobile unit for apheresis is innovative and expands reach and access. Fast track plan for IRB submissions for cell/gene therapy was also advantageous and thoughtful. • Potential manufacturing concerns. Does the Alpha Clinic partner for this effort have the capabilities needed? Level of cell manipulation capabilities is unclear. • Strength: The applicant health system covers the Inland Empire, covering 4 counties (29.3% of the California's land area) and serves a diverse community of >4.5 million residents. The counties consistently rank below the California average for health outcomes and factors. • The applicant presentation improved the feasibility issue by showing the granular detail of the patient population. • Key Strengths: The proposal uses existing FACT-accredited infrastructure and taps into a wide range of clinical and community partnerships to recruit from diverse, underserved populations, including minorities and rural areas. • The work proposed includes specific innovations such as local point-of-care (POC) manufacturing of cell, gene, and regenerative medicine (CGRMT) products in partnership with an Alpha Clinic, plus local ability to perform specialized intracerebral delivery, as ways to de-risk POC medicine. • The scope and culturally relevant community outreach & engagement (COE) program are bolstered by trained community health workers (CHWs) and navigators who use evidence-based approaches (e.g., "Be the Cure" campaign) and detailed plan for small enough workforce, development which includes workforce development and multi-level training strategies. • There is a governance structure, quality management system, evaluation frameworks with real-time data collection, feedback from community scientists, and ongoing process improvement. • A reviewer lauded the contingency plans and institution commitments for funding and operational risks; these show the financial viability (stability-sustainability) of the proposal. • Minor weaknesses: The team will need to monitor their communications plan, risk mitigation and management plans. Operational risks can be present in timely establishment and scaling of decentralized GMP manufacturing and related intra-cerebral navigation system. These involve coordination of teamwork and complex integrations of technology. • Although there is a detailed plan for community engagement, difficulties related to overcoming mistrust and maintaining participation of underserved communities may impede meeting enrollment expectations. • There are institutional resources noted in the budget narrative of this proposal, but it could provide better detail on sustainability outside of grant funding especially while cell, gene and regenerative medicine (CGRMT) is developed. • The staff augmentation plan has several "to be named" key hire placeholders that could unnecessarily introduce uncertainty into the implementation of project if they are not hired early.



- The applicant network is a strength, and the center will serve an important community.
- Strengths: workforce expansion planned across the centers proposed activities (e.g., clinical manufacturing) and people (e.g., nurses, clinicians and others).
- Weaknesses: capacity building is not sufficiently detailed including that for the mobile care manufacturing unit.

Value Proposition

- This proposal is well designed to make a huge impact serving the under-served populations of the Inland Empire.
- The geographic expansion is a critical factor.
- The plan outlines excellent career development opportunities. There COE plan focuses on building trust.
- Strengths: The grant proposal represents a very effective method to broaden local clinical trial access to a large underserved region containing significant minority populations. It allows for centralizing options for coordination, patient navigation, workforce training, IRB fast-tracking and unique local GMP manufacturing capability. The plan addresses multi-level stakeholder needs (patients, providers, sponsors), with strong community-based navigation/outreach components.
- This CCCE directly targets one of the largest and most underserved regions in CA, mitigating travel burdens and addressing a critical geographic access gap. Built in tele-health program, local delivery abilities, on-site clinical and cell processing resources explicitly address the problem.
- This represents the only FACT-accredited regional center in IEDR which adds new community access, unique GMP/POC cell manufacturing, and expertise with underrepresented populations.
- Career development initiatives, diversity outreach, and bidirectional partnerships are clear paths to expanding CIRM's clinical network value.
- Minor weaknesses: Some operational features (e.g., remote-delivery partnerships, career development initiatives) require clearer benchmarks to allow for assessment of ongoing value delivered to sponsors.
- Expansion success relies on ongoing and effective performance from all partnerships. Bottlenecking could happen if recruitment or outreach components don't function properly.
- The extent to which the hospital's innovations can be successfully transferred to members of the Clinical Infrastructure Network (CCIN) will be determined by the quality of integration and knowledge-sharing frameworks created.
- Strength: The applicant team has prior appropriate experience conducting clinical trials and presents an organized operational plan feasible for execution.
- The proposed center has the potential to strongly impact availability of cell & gene therapy clinical trials to patients in a larger region of southern California that is currently underserved. The proposal builds on an already established system for community patient outreach, workforce training and clinical trial recruiting to expand to include CIRM cell and genetic therapy clinical trials. In addition, the application would add GMP manufacturing capability through co-funded investment in infrastructure, equipment and manufacturing development along with partnerships with existing Alpha Clinics.

Plan and Design

- The workforce training plan is a major strength.
- Strengths:
Plan leverages existing dedicated space, integrated IT/EMR systems, Fast Track IRB, and multidisciplinary team for better streamlined access for patients and logistics.
Ability to clearly navigate and schedule and solid systems in place to support trial follow-up and protocol adherence.
- Existing local GMP capabilities and established standards/processes related to cell/gene therapy product handling indicate that the operation proposed is well positioned and ready for full operation. Experience based on external collaborations for regulatory submissions, production, release, and quality.
- Multiple targeted pipelines: physician fellowship, Community Health Worker (CHW) certification, in-house/partner educational collaborations, outreach to underrepresented backgrounds.
- Embeds career advancement and workforce diversity development as major thrusts.
- Detailed, culturally tailored COE plan based on incorporating >50 Community Based Organizations (CBOs), multilingual programming, integration with CHWs/promotores, evidence-based campaigns. Embedded participatory advisory group and ongoing feedback model.
- Partnerships with CBOs and FQHCs address economic, transportation, linguistic, and social determinants of health barriers; navigation includes housing and financial support resources.
- Inclusion of financial navigation, transportation, and "warm handoff" protocols strengthens impact.
- Formalized partnerships and active referral/consultation arrangements with multiple Alpha Clinics, joint cell manufacturing, and cross-staff training activities.
- Shared operational models and patient navigation models.
- Comprehensive logic-model-driven mixed-methods evaluation, regular quarterly reviews, and transparent bi-directional reporting to all stakeholders are adequate.
- Use of validated navigation tools, satisfaction surveys, and detailed data tracking are appropriate.



- Minor weaknesses: Complicated integration of new manufacturing operations and outreach could incur delays during the initial start-up. Execution will rely upon scalable staffing and a lack of encumbered communication with other departments or partner sites.
- New GMP facilities and processes may pose risks of unanticipated technical, regulatory, or staffing delays that can impact trial timelines.
- Measuring downstream workforce retention and effectiveness depends on robust data tracking and sustained engagement with trainees.
- Results hinge on sustained engagement and explicit referral-to-enrollment numbers; possible overextension of funding for new outreach when scaling up.
- Effectiveness will depend on process fidelity, sustained funding for navigation/support services, and ongoing engagement with the network.
- Partnership roles and the pace of cross-integration will need ongoing monitoring.
- The plan may need further specification on how lessons learned are disseminated statewide and fed into other sites on an ongoing basis.
- Strength: Presents centralized options for coordination, patient navigation, workforce training, IRB execution and local manufacturing capability.
- The proposal has a well thought-out plan with three focus areas: 1. Clinical trial support 2. Community engagement 3. Training programs. Each focus area is well planned, with many building on existing frameworks already in place. Details for each in subsequent bullets.
 - Clinical trial support: this health system currently conducts research across various diseases and clinical trials phases. They have a dedicated cancer center research department (with dedicated cell/gene therapy clinical trial unit) and a general Clinical Trial Center. They plan to centralize coordination and administration of CGRMT clinical trials, establish a fast-track IRB process, build dedicated space for clinics and infusions to support CGRMT trials and a bio-repository laboratory, and develop a POC GMP cell processing capability.
 - Community engagement: will employ a multi-level, bilingual outreach strategy utilizing both in-reach and community-based outreach. They will leverage their existing primary care and clinic networks to reach patients, deploying CHW and navigators from El Sol to local events. They plan to implement a Community-to-Trials Pathway and Clinical Navigation Hub and a Community Scientists Advisory Group.
 - Training programs - will expand workforce that delivers CGRMT by applying education as a career development strategy. The CCCE will train and advance knowledge in comprehensive services specific to CGRMT delivery and clinical trials. They will apply this approach to hospital staff, and make it available regionally and to whole California. They will establish a gene and cell therapy career pathway within their institution to ensure a talent pool that can sustain the program and expanded patient access for years to come
- Very appropriate CCCE plan.
- Well-designed project to ensure enrollment in clinical trials of various sorts especially through various partnerships,

Feasibility

- Showing the patient population detail related to the Alpha Clinic trials is a major strength.
- Strengths:
A clear multi-year timeline with upfront infrastructure activities; builds on existing institutional clinical, operational, and IT systems.
Backup/contingency plans and institutional support are described in detail.
- Strong institutional record of >500 active trials, including CGRMT; FACT-accredited, dedicated personnel, and shown compliance for complex trials. Track record of successful recruitment and retention of most underserved and minority cohorts in pinpointed disease/therapeutic areas.
- Diverse, multidisciplinary team with clinical, regulatory, outreach, and technical leadership; roles are clearly assigned and expertise is broad.
- Engagement of national and regional leaders in community engagement and GMP operations.
- On multiple levels, access to institutional, philanthropic, and in-kind resources were successfully described including matching funds, space, IT, staff and capital assets. The multi-level partnerships ensure broad access to community, clinical, and manufacturing resources.
- Minor weaknesses:
The timeline has a risk of delay for GMP operationalization and/or outreach program scale-up, relying on quickly aligning multiple stakeholders and external partners. Risk mitigation and communications plan will be needed.
- Heavy reliance on existing staff; sustainability as new projects scale or staff are pulled into new parallel projects is a potential/future concern.
- Some positions are “to be named”—timely recruitment and onboarding of specialized roles (e.g., manufacturing technicians, navigators) will be critical.



- Long-term sustainability - in particular for outreach and navigation, beyond the current pilot and complex community engagement infrastructure, is likely to depend on ongoing access to external funding or billing revenue streams post-grant.
- Concern: Success relies on effective partnerships from all partners; additional contingency planning with more emphasis on monitoring and risk mitigation would be helpful.
- Strength: Track record of successful recruitment and retention of underserved populations.
- The approach seems very feasible. The host institution has a strong clinical and outreach program in place and their proposal extends its capabilities to CIRM cell and gene therapy trials. The biggest novel development will be the implementation of POC GMP manufacturing and that will be through collaboration with an experienced site.
- This proposal seems quite feasible.

Serving the Needs of California Patients and Affected Communities

- This is a highly underserved region.
- Strengths: Proposal addresses major barriers to access with local delivery, support with community outreach, navigation and financial/logistics accessible - addressing clear needs of underserved patient populations. Proposal is clearly based on proven strategies and includes innovative interventions for IEDR.
- The applicants will use EMR-based cohort identification, COSMOS system software, extensive primary/specialty clinic networks, and embedded bicultural navigators. Multilingual, culturally tailored materials and campaigns are built into outreach plans.
- The CCCE will deploy an embedded community scientist advisory group, regular bi-directional protocol and material review, COE team with relevant expertise, and participatory program design.
- Prior track record in patient engagement and research in minority health disparities in place.
- Minor weaknesses:
Referral to enrollment conversion may be slow to full scale; results will depend on ongoing effectiveness and monitoring of outreach programs.
- Complete inclusion requires ongoing community advisory feedback and nimble adjustment of recruitment strategies if sub-cohorts are underutilized.
- Maintaining ongoing engagement and honoring feedback from all sociodemographic groups requires proactive and constantly evolving strategies.
- Strength: Culturally tailored and multilingual programming, CHWs/promotores, and evidence-based educational campaigns are proposed with significant detail.
- Strength: Proposed tele-health program, local delivery abilities, on-site clinical, and cell processing resources will directly address access by underserved populations to cell and gene therapies.
- The team has a well thought out and executed referral strategy that has already showed success with non-C> clinical trials. Their experience with patient outreach and the partnership with community health workers and local community groups will be a benefit to the program.
- The proposed infrastructure addresses a wide geographic region with unmet need and includes capacity for holistic (including cell processing / manufacturing and patient care) point-of-care clinical trial therapeutics delivery.
- The extremely robust and detailed community engagement plan partners with health concern groups like American Cancer Society, local community groups, and advocacy groups. They will partner with an Alpha Clinic's Community Outreach and Engagement Plan team with demonstrated capacity to organize large-scale outreach events, adapted evidence-based education for diverse audiences, and navigate complex individual and systemic barriers to access. Navigators and CHW are trained in cultural humility, trauma-informed communication, and health literacy to ensure they can engage patients effectively. Similar approach will be utilized in the IEDR COE with planned transfer of expertise capitalizing on their partner Alpha Clinic's extensive experience implementing equitable outreach and navigation strategies. The COE will be embedded in the communities it serves. Community-based partners— include CBOs, FQHCs, and faith groups.
- The COE team and plan, based on successful models, will create a "Be a Part of the Cure" Campaign developed by local community advisory boards. This outreach plan is robust and creative. Their use of community workers including promotores is well-conceived and should yield community trust.
- This plan clearly focuses and listening to patient and community voices in planning, executing and maintaining the proposed facility. They are very careful to detail how exactly they will engage each different community group including the San Manuel Indian tribe.
- Overall, the host institution and their partners have done an outstanding job of describing how their facility will serve the needs of Inland Empire patients and communities.



Application #	GWG INFR8-18823
Title (as written by the applicant)	Establishing a CIRM Community Care Center of Excellence in the Central Valley
Project Objective (as written by the applicant)	A Community Care Center of Excellence will expand local access to gene and cellular therapies for a diverse and underserved part of California. This initiative will bring cutting-edge gene and cellular treatments to patients, eliminating the need for long-distance travel for therapy access.
Summary (as written by the applicant)	<p>The creation of a CIRM Community Care Center of Excellence (CCCE) in the Central Valley will revolutionize local healthcare access by delivering cutting-edge gene and cellular therapies to diverse and underserved California populations, removing geographic barriers that have long denied them access to these life-changing treatments. Currently, these therapies are restricted to those with the financial means and ability to travel to distant academic centers—an unacceptable disparity. The center will serve as a model for community-based regenerative medicine, contributing operational insights and outcomes to CIRM’s learning network.</p> <p>Our vision is to establish a local CCCE for gene and cellular therapies, expanding accessibility of these treatments to patients in Central California while developing a skilled local workforce. To implement this vision, the CCCE will be based at an outpatient cancer institute alongside clinic services and trials, patient navigation, and a cell-processing lab. The program will be led by a multidisciplinary team and community partners to deliver care, conduct research, and train the next generation of regenerative medicine professionals.</p> <p>A key component of the project is the creation of a state-of-the-art, on-site cell processing facility with point-of-care manufacturing capabilities, fostering local independence in delivering these complex therapies in Central California. The CCCE will create access to gene and cellular therapies for individuals who otherwise would need to travel at least 200 miles for services—an unfeasible travel burden for those with limited financial means and lack of available transportation. These barriers currently make advanced gene and cellular therapies largely unattainable for a vast majority of Central Valley residents.</p> <p>This project will increase the percentage of eligible patients in Central California who receive these transformative treatments, addressing a critical unmet need where currently only a small fraction benefit. In parallel with our infrastructure development, we will engage trusted community-based organizations to build awareness of clinical trials and treatment availability to ensure that underserved populations are reached and access is truly equitable.</p> <p>In collaboration with CIRM Alpha Clinic programs, the CCCE will cultivate a skilled local workforce to ensure broad access to approved and investigational cell and gene therapies. Workforce development will include training on regulatory and accreditation processes, quality assurance, and facility operations. By optimizing our clinical research capabilities, we will increase participation as a treatment site in active cell and gene therapy clinical trials, bringing these advancements closer to home. While initial treatments will focus on cancer, specifically chimeric antigen receptor T-cell (CAR-T) therapy, the CCCE will enable future gene and cellular therapies to treat an array of conditions, including neurological diseases.</p>
Statement of Benefit to California (as written by the applicant)	A Center of Excellence in Central California will fundamentally transform access for thousands of the state’s citizens. Currently, patients needing advanced gene and cell therapies must endure costly journeys away from their crucial support networks, often leading to financial hardship or forgoing care entirely. This project directly addresses a critical geographic and access gap, ensuring that diverse, underserved, and underrepresented populations can receive these treatments close to home.
Funds Requested	\$8,996,101
GWG Recommendation	Recommended: Exceptional merit and warrants funding, if funds are available
Process Vote	<p>All GWG members unanimously affirmed that “The review was scientifically rigorous, there was sufficient time for all viewpoints to be heard, and the scores reflect the recommendation of the GWG.”</p> <p>Patient advocate members unanimously affirmed that “The review was carried out in a fair manner and was free from undue bias.”</p>



SCORING DATA

Final Score: 87

Up to 15 scientific members of the GWG score each application. The final score for an application is the median of the individual member scores. Additional parameters related to the score are shown below.

Mean	87
Median	87
Standard Deviation	3
Highest	90
Lowest	80
Count	12
Tier 1 (85-100): Exceptional merit and warrants funding, if funds are available	11
Tier 2 (1-84): Not recommended for funding	1

KEY QUESTIONS AND COMMENTS

Proposals were evaluated and scored based on the key questions shown below, which are also described in the PA/RFA. Following the panel's discussion and scoring of the application, the members of the GWG were asked to indicate whether the application addressed the key question and provide brief comments assessing the application in the context of each key question. The responses were provided by multiple reviewers and compiled and edited by CIRM for clarity.

<p>Key Strengths and Weaknesses</p> <ul style="list-style-type: none"> • The establishment of partnerships with community-based organizations (CBO) will reach underserved and underrepresented groups, including Latinx, Black, Southeast Asian, Native American, and Veteran communities. • The CCCE will expand support to patients with other conditions, i.e. patients with sickle cell disorders and patients with complex neurological conditions. • The applicant will work with 2 Alpha Clinics' program staff, will recruit and train staff to deliver approved and investigational cell and gene therapies for various conditions. • Key strength: Location and relationship with the Alpha Clinics. • Strengths: Serving a clear need in Central CA, and for underserved populations, plan for workforce development. • Strength: Will expand geographic access to central CA (the Central Valley), consisting of a 15,000 square mile area with 1.7 M residents. Another strength is that training in apheresis will be offered with program certification. • Main weakness: Insufficient information provided to evaluate approach (e.g., lack of descriptions for key elements and processes), rigor of methods (e.g., to establish new manufacturing capabilities), and likelihood of success of various aspects of the proposal. (e.g., training programs, enrollment of new research subjects, etc).
<p>Value Proposition</p> <ul style="list-style-type: none"> • The proposal will significantly expand geographic access to central CA (the Central Valley) for regenerative medicine treatments and clinical trials, specifically to a 15,000 square mile area which is home to 1.7 M Californians. • The applicants' host institution currently serves a vast 15,000-square-mile region with 1.7 M residents who face significant health disparities and limited access to healthcare. • The proposed new decentralized GMP facility will expand the value of CIRM's Clinical Infrastructure Network by significantly broadening the Network's reach to a new geographic region, notable for the fact that 20% of residents live below the poverty line and half rely on government insurance. • The proposed CCCE could positively impact the central valley region of CA and bring value to populations that have no access to larger centers. In addition, new regenerative medicine manufacturing capabilities and offering new career development opportunities are both planned. • The new Center will help develop a new workforce, including establishing a new fellowship, and provide new expertise for the 5 years of the award and beyond. There is a plan to work with CBOs and build trust, respect and new capabilities including local manufacturing capabilities (e.g., local cell processing, testing, product delivery). • In summary, the proposed center is highly ambitious and offers an impactful and practical value proposition for underserved patients, including mostly minoritized patients (especially Latinx) who experience health disparities, as well as for trial sponsors and health care providers who do not currently have access to populations needing regenerative medicines and access to trials in central CA currently.



- Having lived and worked in the Central Valley, this reviewer finds this proposal extraordinarily impactful to an area that is quite underserved in many areas including medical and research needs. The plan of collaboration between advanced medical facilities and community-based organizations seems very practical.
- The proposal is exactly what in this reviewers' estimation is needed to expand access to geographic access.
- The proposed center does everything that one would hope for: it greatly broadens the network's reach to an area with acute needs; it develops significant training opportunities to an area with a shortage of medical personnel, and it reaches out to communities to groups which, particularly in today's climate, have huge trust issues with established authorities. It will do this in part by partnering with community based organizations.
- Strength: Will expand geographic access to central CA (the Central Valley), consisting of a 15,000 square mile area with 1.7 M residents. Concern: Systems in place, but metrics not outlined for regulatory processes/delivery of therapeutics.
- [redacted University GMP facility] will deliver essential staff training in quality assurance, facility operations, and manufacturing at its GMP facility, and offer an online cell and gene therapy certification course. It is not clear who on the CCCE side will be responsible for running the GMP facility. There is no organizational setup presented for the GMP facility. It was stated that applicant will operate as a satellite site under shared oversight. This was not detailed and therefore, presents a gap in the application.
- A minor weakness is that it remains unclear how the learning from this proposal will inform future work beyond hematology/oncology, such as in the neuroscience space which was mentioned.

Plan and Design

- Through partnerships with the 2 Alpha Clinics, training will be provided for a hematology/oncology fellow in cellular therapy, as well as for physicians and nurses in apheresis, infusion, and complication management.
- The proposal is deeply focused on expanding the manufacturing capabilities at this site, which would expand access to RMs in this area. The plans appear appropriate in order to expand capabilities first and then begin outreach and trial initiations.
- Clinical operations are appropriately planned, from co-design and iterative improvements, to expand the accessibility of regenerative medicine treatments. For example, training in apheresis and other specialized techniques will be offered, with program certification, and while taking a holistic approach (from bench to bedside), meeting the needs of individual patients (e.g., including with a navigator to address housing, food, financial, and other practical needs).
- The proposed career development activities serve to develop the workforce integral to the delivery of regenerative medicine treatments, including training of various staff, nurses, and physicians. There will be certificate programs and a new, non-ACGME accredited clinical fellowship in cell therapy, with the partnered Alpha Clinic.
- The proposed community-based partnerships plan to address informational, economic, and other determinants impacting access to regenerative medicine treatments. For example, new partnerships are already being formed with local CBOs. Information sharing is being planned, including in the language and cultural context relevant to the local populations. These partnerships help build trust with minoritized patients and families and help increase access to regenerative medicine.
- The applicant proposes a collaboration with CIRM Alpha Clinics to assist patients in accessing clinical trials and approved treatments.
- The evaluation plan and schedule are well developed and appropriate to collect and synthesize operational information, optimize center operations and enable effective knowledge sharing. The timeline is realistic and milestones are clear. A reasonable logic model is outlined. The metrics of success are well described.
- Since the clinical operations will be planned and built on the foundations of an existing care network, it seems very well designed to bring the value of clinical trials to the Central Valley which, as mentioned previously, has no access to regenerative medicine treatments except travel to Los Angeles Metro area or the Bay Area.
- Based on its recent successes with its CAR-T treatment program, applicants have developed a reasonable plan to succeed within the project timelines.
- The career development plan, given the staff shortages in the Central Valley, is a crucial component of this project. The proposed partnerships with both University of California campuses in direct and digital training programs seems innovative and useful.
- The outreach and engagement plan is to me one of the great strengths of this proposal. The applicant plans on building on host institutions' existing community care network and partnerships with community-based organizations to develop outreach and engagement which will target the underserved populations especially the 57% Hispanic population of the area. The outreach to undocumented populations (of which there are a significant number) will be especially challenging.



- The group has spent a great deal of effort to build on its network of current clinical sites and partnerships with community-based providers to address all of the determinants affecting access to care.
- The collaboration with the 2 Alpha Clinics is key to the success of the program being presented.
- The plan for knowledge sharing, given the obvious partnerships with academic research centers, is very impressive.
- Concern: Educational curriculum/workforce development not outlined other than establishment of fellowship.
- There will be a heavy reliance on Alpha Clinics for training in all aspects of the program.
- A few weaknesses noted:
 - The plan to manage investigational or approved regenerative medicine products within the project timeline is briefly outlined but not detailed.
 - The workforce development plan, for example for the new fellowship, remains vague.
 - While it is expected that the new center will increase referrals of CA patients to regenerative medicine treatment opportunities, it is not articulated to what extent the proposed outreach and engagement activities will increase such referrals (e.g., no estimate of number of new referrals expected by year, etc.)

Feasibility

- The proposed activities will focus on 6 measures: recruiting and training staff, developing regulatory processing (such as expertise, accreditation, quality assurance, facility operations, and manufacturing readiness), creating a new fellowship, establishing partnerships with CBOs, establishing on-site cell and gene therapy services, and expanding the team/building expertise.
- A formal collaboration with the listed Alpha Clinic and GMP lab facility will establish a lab for processing cellular therapy and point-of-care manufacturing adjacent to host institution's apheresis center. This approach will create the Central Valley's first local CAR-T manufacturing site, improving access and reducing delays for rural and underserved patients.
- It should be noted that in November 2024, the applicant launched a comprehensive CAR-T treatment program, achieving Kymriah certification. They have provided treatment to two patients. Over three years, the apheresis, laboratory, and nursing teams underwent rigorous training, including shadowing [redacted university medical center] stem cell transplant and cellular therapy teams. Preparation focused on apheresis procedures, product handling, and infusion administration, ensuring patient safety and treatment efficacy.
- The [redacted university's oncology research department], located within host institution, has extensive clinical research infrastructure and expertise. The department is well-established, with a dedicated team of clinical research coordinators, research assistants, and regulatory staff supporting a diverse portfolio of clinical trials across solid and hematologic malignancies. It has a strong track record of conducting both industry-sponsored and NCI cooperative group trials, demonstrating its capacity to manage complex, multi-site research protocols. This will be extensively leveraged by this CCCE in its endeavors to be a gene and cell therapy center.
- The project plan appears feasible and is likely to be implemented within the timelines proposed. The team and the site have some experience with CAR-T treatments already.
- The applicant team includes MDs, nurses, social workers, and others, making it likely that the team will be able to successfully develop and operate the proposed CCCE.
- The team will have access to the necessary resources to develop and operate the CCCE, support patients, career development, outreach and engagement programs and community-based partnerships.
- The applicant appears to be relatively new to conducting clinical trials, but its key partners, of course, have very extensive experience, so I think the proposal is viable.
- The team proposed seems to be very strong, and it includes specific staff to conduct the outreach activities which will be crucial to the success of the project.
- The proposed team, in conjunction with its academic and community partnerships, has the resources for expanding Central Valley career development, outreach, and patient support.
- Concern: Hierarchy is not defined as to who will lead facilities, and no subject matter experts are listed.
- Because of a lack of detail around the manufacturing feasibility, i.e. no design sketch, the plan may be ambitious in its timeline to obtain FACT accreditation.
- Some weaknesses: Most of these measures are feasible in 5 years, but the second about regulatory processes will be a heavy lift, and because no metrics are provided for any of the measures, it remains questionable if they will be achieved.
- The applicant's bio states that they have conducted "many" clinical trials, but an estimate is not provided, and no examples are given, making it unclear that they have the appropriate experience in conducting clinical trials.
- The project plan has enough detail to appear to be quite feasible. This reviewer's only hesitation is that they do not see a clear source described for the \$2 million philanthropic contribution.

Serving the Needs of California Patients and Affected Communities



- The CCCE will provide, if successful, a big outreach to communities with grave needs in the Central Valley.
- This will establish a gene and cell therapy career pathway within the host institution to ensure a talent pool that can sustain the program for years. With higher numbers of trained professionals, more patients will be able to access services.
- The CCCE will offer rotations for trainees from CIRM-funded education programs such as Bridges, SPARK, and COMPASS, covering clinical navigation, GMP operations, and outreach.
- There is significant potential to expand access to underserved patients with the proposed plans and resources, including collaboration with 2 Alpha Clinics.
- The proposed activities is likely to increase referrals and patient access (e.g. enrollment) to clinical trials or approved treatments.
- The project team will bring perspectives and experience from affected populations to the implementation of proposed activities, through the CBOs.
- The proposal will greatly expand the potential to increase referrals and patient enrollment in clinical trials. The Central Valley has a large population (1.7 million) with no current access to regenerative care.
- The specific plan and team being put together carefully lays out how it will approach the Hispanic and other underserved groups in a variety of ways to facilitate recruitment.
- Since the applicant organization is already sponsoring a network of community-based clinics, it brings extensive experience in using the perspectives and experience of patients to the implementation of the project.
- Concern: Activities and methods to elicit stakeholder feedback is not well defined; unclear if iterative feedback mechanism are in place to elicit community engagement, feedback, and perspectives.
- Concern: Role of dedicated CCCE patient navigator is unclear given large service area and community of service proposed.
- Weakness:
 - Not clear if patient experiences will affect implementation.
 - The tools and resources to engage and recruit patient cohorts that encompass all affected populations remain vague (e.g., it is unclear what specific tools or resources will be used for the Latino population, for the non-English speaking Southeast Asian population, for the under-insured, etc.).



Application #	FWG INFR8-18823
Title (as written by the applicant)	Establishing a CIRM Community Care Center of Excellence in the Central Valley
Project Objective (as written by the applicant)	A Community Care Center of Excellence will expand local access to gene and cellular therapies for a diverse and underserved part of California. This initiative will bring cutting-edge gene and cellular treatments to patients, eliminating the need for long-distance travel for therapy access.
Summary (as written by the applicant)	<p>The creation of a CIRM Community Care Center of Excellence (CCCE) in the Central Valley will revolutionize local healthcare access by delivering cutting-edge gene and cellular therapies to diverse and underserved California populations, removing geographic barriers that have long denied them access to these life-changing treatments. Currently, these therapies are restricted to those with the financial means and ability to travel to distant academic centers—an unacceptable disparity. The center will serve as a model for community-based regenerative medicine, contributing operational insights and outcomes to CIRM’s learning network.</p> <p>Our vision is to establish a local CCCE for gene and cellular therapies, expanding accessibility of these treatments to patients in Central California while developing a skilled local workforce. To implement this vision, the CCCE will be based at an outpatient cancer institute alongside clinic services and trials, patient navigation, and a cell-processing lab. The program will be led by a multidisciplinary team and community partners to deliver care, conduct research, and train the next generation of regenerative medicine professionals.</p> <p>A key component of the project is the creation of a state-of-the-art, on-site cell processing facility with point-of-care manufacturing capabilities, fostering local independence in delivering these complex therapies in Central California. The CCCE will create access to gene and cellular therapies for individuals who otherwise would need to travel at least 200 miles for services—an unfeasible travel burden for those with limited financial means and lack of available transportation. These barriers currently make advanced gene and cellular therapies largely unattainable for a vast majority of Central Valley residents.</p> <p>This project will increase the percentage of eligible patients in Central California who receive these transformative treatments, addressing a critical unmet need where currently only a small fraction benefit. In parallel with our infrastructure development, we will engage trusted community-based organizations to build awareness of clinical trials and treatment availability to ensure that underserved populations are reached and access is truly equitable.</p> <p>In collaboration with CIRM Alpha Clinic programs, the CCCE will cultivate a skilled local workforce to ensure broad access to approved and investigational cell and gene therapies. Workforce development will include training on regulatory and accreditation processes, quality assurance, and facility operations. By optimizing our clinical research capabilities, we will increase participation as a treatment site in active cell and gene therapy clinical trials, bringing these advancements closer to home. While initial treatments will focus on cancer, specifically chimeric antigen receptor T-cell (CAR-T) therapy, the CCCE will enable future gene and cellular therapies to treat an array of conditions, including neurological diseases.</p>
Statement of Benefit to California (as written by the applicant)	A Center of Excellence in Central California will fundamentally transform access for thousands of the state’s citizens. Currently, patients needing advanced gene and cell therapies must endure costly journeys away from their crucial support networks, often leading to financial hardship or forgoing care entirely. This project directly addresses a critical geographic and access gap, ensuring that diverse, underserved, and underrepresented populations can receive these treatments close to home.
Funds Requested	\$8,996,101
FWG Recommendation	Recommended: warrants funding
Process Vote	All FWG members unanimously affirmed that “The review was scientifically rigorous, there was sufficient time for all viewpoints to be heard, and the scores reflect the



	<p>recommendation of the FWG.”</p> <p>Patient advocate members unanimously affirmed that “The review was carried out in a fair manner and was free from undue bias.”</p>
--	--

SCORING DATA

Final Score: 90

Up to 15 scientific members of the GWG score each application. The final score for an application is the median of the individual member scores. Additional parameters related to the score are shown below.

Mean	89
Median	90
Standard Deviation	6
Highest	95
Lowest	80
Count	7
Tier 1 (85-100): Exceptional merit and warrants funding, if funds are available	6
Tier 2 (1-84): Not recommended for funding	1

KEY QUESTIONS AND COMMENTS

Proposals were evaluated and scored based on the key questions shown below, which are also described in the PA/RFA. Following the panel’s discussion and scoring of the application, the members of the FWG were asked to indicate whether the application addressed the key question and provide brief comments assessing the application in the context of each key question. The responses were provided by multiple reviewers and compiled and edited by CIRM for clarity.

Key Strengths and Weaknesses	
<ul style="list-style-type: none"> • Strong team, with a good plan using an existing facility with a modular clean room. • Strength: Associated team and consultants are experienced within this field Weakness: No supporting documentation on costs, plans, or equipment justification. • Collaborations with multiple very strong partners in cell and gene therapy centers and architects/contractors experienced in GMP construction) are very reassuring. • The large catchment area, almost all which can be described as underserved, definitely supports goals of CIRM's CCCE program. Drive times to nearest GMP facility (-ies) is too long. • There is strong support for the location and partners, with some argument about facilities setup. 	
Appropriateness of the renovation and facilities improvement project to support the proposed CCCE activities	
<ul style="list-style-type: none"> • The renovations support project goals well, and the location is very appropriate for a CCCE. • The scope of work and the location are exactly what CCCE is hoping to achieve. A vastly underserved area will receive a first-class facility and program. • Renovations directly support the CCCE, but there are minimal plans and the narrative to justify such a technical build and its costs as presented are lacking. • The location is appropriate; the layout is likely appropriate but unjustified. 	
Feasibility of the proposed renovations/facility improvements	
<ul style="list-style-type: none"> • The schedule is very reasonable and the application has an experienced team. • The milestones and timelines seem ambitious but achievable. The project seems very well staffed. • The quality of the experts involved in design and construction support the timeline estimates and the ability to satisfy the requirements associated with GMP facility construction. • If the proposed GMP facility is a modular plug and play solution, it is feasible that the timelines can be met (although this is not explicitly stated in the application). For a "ground up" construction of a GMP facility, it is not nearly enough time. 	
Appropriateness of the renovation/facility improvement costs	
<ul style="list-style-type: none"> • Costs are conservative but probably are the right numbers. 	



- The costs seem appropriate; my only question had to do with the reliability of the potential donated resources.
- It's impossible to know, if costs are appropriate. There is no breakout of design nor construction costs. What equipment is listed as necessary is the most expensive, gilded version applicable.
- Prevailing wage is unaddressed.
- A single number only is given for total cost of the program, without breakdown or supporting documentation from vendors or contractors. The timeline seems very ambitious, especially with modular engineering done off site, requiring installation and certification.



Application #	GWG INFR8-18783
Title (as written by the applicant)	Community Care Center of Excellence for Regenerative Medicine
Project Objective (as written by the applicant)	Our objective is to expand capacity, workforce development and community outreach to become a Community Center of Excellence for Regenerative Medicine. This will reduce burden and increase access to treatments and clinical trials for patients in rural communities, far from major metropolitan areas.
Summary (as written by the applicant)	This project will identify needs and build capacity to deliver Regenerative Medicine therapies to geographical areas far from the current CIRM-funded Alpha Clinics.
Statement of Benefit to California (as written by the applicant)	The Community Care Center of Excellence for Regenerative Medicine (CCCE) will support delivery of novel therapies to patients, expanding treatment options available to Californians in geographically diverse locations. The CCCE will expand the CIRM Clinical Trials Network, accelerating access to FDA-approved cellular therapies & FDA-authorized clinical trials. Californians outside of major metropolitan hubs will benefit by having access to new treatments for serious diseases and conditions.
Funds Requested	\$8,978,900
GWG Recommendation	Not Recommended: Not recommended for funding
Process Vote	All GWG members unanimously affirmed that “The review was scientifically rigorous, there was sufficient time for all viewpoints to be heard, and the scores reflect the recommendation of the GWG.” Patient advocate members unanimously affirmed that “The review was carried out in a fair manner and was free from undue bias.”

SCORING DATA

Final Score: 80

Up to 15 scientific members of the GWG score each application. The final score for an application is the median of the individual member scores. Additional parameters related to the score are shown below.

Mean	79
Median	80
Standard Deviation	5
Highest	85
Lowest	70
Count	13
Tier 1 (85-100): Exceptional merit and warrants funding, if funds are available	2
Tier 2 (1-84): Not recommended for funding	11

KEY QUESTIONS AND COMMENTS

Proposals were evaluated and scored based on the key questions shown below, which are also described in the PA/RFA. Following the panel’s discussion and scoring of the application, the members of the GWG were asked to indicate whether the application addressed the key question and provide brief comments assessing the application in the context of each key question. The responses were provided by multiple reviewers and compiled and edited by CIRM for clarity.

Key Strengths and Weaknesses
<ul style="list-style-type: none"> In summary, the proposed CCCE will drive equity, innovation, and sustainability in regenerative medicine through inclusive, community-based healthcare, and expanded access to populations that are currently underserved. However, there are few details missing on how these ambitious plans will be implemented. The applicant’s presentation did not clarify specific plans and may have detracted from the proposal’s strengths. Strengths: <ul style="list-style-type: none"> The applicant and site have significant experience in conducting clinical trials. The application includes strong in-kind contributions. Weakness: The timeline would benefit from additional detail on execution of plans proposed. The proposal addresses a very important geographic area. The plan is not adequate.



<ul style="list-style-type: none"> ● Strength: Well-articulated workforce development from bench to bedside. ● Weaknesses: It's not clear what will be done differently as compared to some of the existing resources available, nor where and how cell therapy treatments will be administered. ● Key concerns were related to manufacturing and program readiness.
<p>Value Proposition</p> <ul style="list-style-type: none"> ● Equitable Access & Geographical Expansion: CCCE will overcome barriers like distance, language, and transportation to serve diverse groups—Hispanic, geriatric, rural, LGBTQIA+, and undocumented populations—among the 2.5 million Californians in the county and nearby communities unable to reach existing CIRM Alpha Clinic sites. ● This proposal's essential tool is their collaboration with critical partnerships of various established and trusted community partners. Additionally their mobile unit will allow them to reach an even larger population. ● Strengths: The host institution currently serves 180,000 patients annually, and has capacity to expand to the local region. The sponsor intends to deploy a mobile medical unit to bring access to patients that cannot readily access the location. The sponsor also proposes to offer significant career development opportunities to the current staff and potentially expand their capacity. ● Workforce Development: CCCE will train culturally competent healthcare professionals through partnerships with local academic institutions. A hematology/oncology fellowship launching in July 2026 will complement the applicant institution's 10 existing training programs. Outreach will also target high school students and nurses. ● Community Engagement: Collaboration with local leaders, community health workers, and CBOs to deliver bilingual education, transportation support, and culturally tailored outreach, most of which they already do with current partners. Events like health fairs and partnerships will build trust and reduce stigma around clinical trials. ● CIRM Network Integration: Working with a nearby Alpha Stem Cell Clinic and the broader CIRM network, the proposed CCCE will facilitate knowledge exchange and patient referrals to support statewide regenerative medicine advancement. ● Infrastructure & Expertise: The applicant's FDA-regulated trials experience and advanced facilities will ensure high-quality, patient-centered care while expanding regenerative medicine access. ● The proposed CCCE will drive equity, innovation, and sustainability in regenerative medicine through inclusive, community-based healthcare, expanding access to populations that are currently underserved.
<p>Plan and Design</p> <ul style="list-style-type: none"> ● Infrastructure: The proposed CCCE builds on the host institution's FDA-regulated trials, infusion centers, and cleanroom facilities to support readiness. The Mobile Medical Unit helps to extend care to remote areas, offering screening, education, consent, and follow-up to reduce access barriers. Collaborations with advocacy and community groups foster trust and outreach to underserved populations. Culturally competent outreach through bilingual staff and tailored materials improve communication and reduce language and literacy gaps. Patient navigation services includes transportation, childcare, and trial guidance to eliminate logistical and financial obstacles. Such services are established and do not need to be built from scratch. ● Technology integration through EHR tools to streamline patient identification, recruitment, and trial management for greater efficiency. Decentralized trials allow for embedding trial activities in community settings reducing the need for travel to distant academic centers. Strong models of workforce training include residents, fellows, and nurses on regenerative medicine expertise to support advanced therapy delivery. Partnership with the CIRM network enables shared protocols, resources, and expertise. ● Overall, the lack of details take away from the strengths. ● Strength: Robust description of career development and community outreach activities. Concern: Unclear description of clinical operations and anticipated training protocols and equipment. ● The logistical descriptions of how the clinical operations will be enabled is lacking. There is some mention of equipment that may be needed and protocols for training, but it seems to be lacking on how the current space will accommodate this new process. The timeline is wide, allowing two years for setting up the facility, but it appears that no anticipated locations have been identified. The details are lacking. ● The career development activities are robust. ● It is unclear from the application on how many referrals could be meaningfully increased at the proposed site. The mobile medical unit may become a key factor due to the size of the county and the location of the proposed CCCE, but the deployment timeline is not detailed to show timing of specific activities for successful deployment of this new mobile unit endeavor. ● The applicant intends to collaborate with a nearby Alpha Clinic. ● The 5-year timeline would be required to execute the many plans proposed, but the timelines are lacking significant detail. ● They applicant has shown commitment to reaching numerous diverse populations.
<p>Feasibility</p>



- Details on project execution are lacking. A timeline for major activities would have been helpful; however, the contingency plans mitigated this limitation.
- Academic partnerships support ongoing professional training. A contingency plan addresses delays, staffing, and financial risks, ensuring adaptability and strategies for risk management.
- The project plan is highly feasible and likely to be executed on schedule, supported by a phased timeline providing a clear roadmap from May 2026 to June 2030. It outlines facility setup, workforce training, outreach, and trial launches. The established infrastructure is a strength - i.e., the host institution's FDA-regulated trials, infusion centers, and cleanroom facilities minimize new development needs. Since the early 2000s, its clinical trials office has managed 50+ multi-center studies annually across diverse specialties. Additionally in-kind resources such as existing clinical spaces, trained staff, and EHR technology will contribute to efficient rollout. The host institution's proven track record in clinical care and research reinforces the plan's viability.
- Concern: There are ample resources for support but capacity to deliver is unclear. It's also unclear how much referrals will be meaningfully increased.
- There is little detail in the plans, making it difficult to assess the likelihood of success. The applicant, the team, and the site do have significant experience in conducting clinical trials.
- The feasibility of this project relies on their community partnerships. They have listed organizations with great reach and commitment in their respective communities with consideration to age, income, language, and mental health.
- They are also committed to long-term career growth for professionals to better serve their respective communities.

Serving the Needs of California Patients and Affected Communities

- The proposed activities—including the mobile medical unit, strategic community partnerships, patient navigation services, technology integration, outreach campaigns, workforce development, and collaboration with the CIRM Network—are purposefully designed to reduce participation barriers, raise awareness, and simplify access to regenerative medicine and clinical trials, especially for underserved and rural populations. Collectively, these efforts hold strong potential to boost patient referrals and expand access to both investigational and approved treatments.
- The proposed activities could increase referrals and patient access. More details on the mobile medical unit and the potential population size to be served would have been helpful.
- The proposal emphasizes the importance of outreach with a commitment to "reach all corners of [their] region, especially the most vulnerable". They are collaborating with trusted community partners to focus on their most vulnerable populations and provide culturally tailored information. Their statement that "[a] central pillar of this effort is career development to train and advance a diverse, culturally competent healthcare workforce that begins locally and aims at addressing long-term gaps in access to treatment" is impressive. Taking the time to build deeper community relationships and be present in the community with their mobile unit shows their commitment to establishing long term equity for the whole population.
- Strength: They are partnering with various groups showing that there is not one approach that works for all communities. Special consideration and training is given to language, culture, trauma, access to care, and that training will be a multi-faceted simulation.