



<b>Application #</b>	<b>INFR7-15912</b>
<b>Title</b> (as written by the applicant)	Patient Support Program to Improve Accessibility to Eligible CIRM-Trial Patients
<b>Project Objective</b> (as written by the applicant)	To help improve accessibility to eligible CIRM patients
<b>Summary</b> (as written by the applicant)	<p>The California Institute for Regenerative Medicine (CIRM) is seeking support in the establishment and operations of a Patient Support Program (PSP) and ultimately enhancing patients' accessibility of CIRM-funded clinical trials, particularly for underserved populations.</p> <p>CIRM's goals for this project include:</p> <ol style="list-style-type: none"> <li>1.Helping patients participate in CIRM-sponsored trials by assisting with their travel and care needs.</li> <li>2.Encouraging underserved communities who are less likely to participate in cell and gene trials because of the logistical barriers to enrolling in CIRM trials.</li> <li>3.Assisting trial sites in enrolling patients by providing them with white glove support.</li> </ol> <p>We currently support all services within CIRM's project scope and would like to highlight the following key components of our offering:</p> <ul style="list-style-type: none"> <li>• Ease of patient intake and enrollment through our multi-channel engagement platform.</li> <li>• Automated eligibility screening that will provide financial and logistical transparency to patients and caregivers. Our patient support navigators (PSNs) will provide a detailed itinerary for travel logistics.</li> <li>• Flexible payment options to reimburse patients based on eligible expenses. We recommend virtual debit cards as a user-friendly and low-cost option to CIRM.</li> <li>• Daily reporting of disbursement, reimbursements, enrollment, demographics, program activity, key performance indicators (KPIs), call reports and trial statistics.</li> <li>• Focus on diversity, equity and inclusion through careful consideration in program design to improve access to trials for underserved and disproportionately affected populations</li> </ul>
<b>Statement of Benefit to California</b> (as written by the applicant)	This project will allow patients in underserved communities in California equal access to clinical trials without bias due to financial circumstances.
<b>Funds Requested</b>	\$2,485,000
<b>AAWG Recommendation</b>	Tier 1: warrants funding
<b>Process Vote</b>	<p>All AAWG 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 AAWG."</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: 1

Up to 11 members of the AAWG score each application. The final score for an application is the majority score of all of the individual member scores. If there is no majority score, the final score is 2. Additional parameters related to the score are shown below.

<b>Highest</b>	1
<b>Lowest</b>	2
<b>Count</b>	13
<b>Votes for Tier 1</b>	7
<b>Votes for Tier 2</b>	6
<b>Votes for Tier 3</b>	0



- A score of “1” means that the application has exceptional merit and warrants funding.
- A score of “2” means that the application needs improvement and does not warrant funding at this time but could be resubmitted to address areas for improvement if the ICOC has not approved an application for funding following the AAWG review.
- A score of “3” means that the application is sufficiently flawed that it does not warrant funding.

## 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 AAWG 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.

AAWG Votes	Does the application offer a meaningful value proposition to improve access and retention to CIRM-funded clinical trials through its proposed patient support services?
<p><b>Yes:</b> 5 <b>No:</b> 1</p>	<ul style="list-style-type: none"> <li>• They appeared to be excited about the project and provided support examples of other successes</li> <li>• The applicant describes a "white glove, concierge" patient-centric experience that is very attractive. Their long-experience in the patient support space, including supporting ultra rare and Cell &amp; Gene Therapy (CGT) programs, speaks to a level of preparedness necessary to partner with CIRM on this project. The case study of implementation of a program to support a cell therapy program is appreciated.</li> <li>• Strong emphasis on minimizing patient impact and burden. Reliance on technology to accomplish this may not work for all participants. Careful discussion as to how they support non-tech savvy participants is needed.</li> <li>• Experience with rare disease patient populations. Specific mention of partnering with Community Benefit Organizations to provide additional support for participants.</li> <li>• The proposer has established structures that can be adopted. Careful consideration of the applicants ability to partner with CIRM in critical decisions is important.</li> <li>• The extent to which applicant is relying too heavily on technology without enough manual support for patients who need personal interaction rather than technical interface is unclear.</li> <li>• Digital Concierge tool may be a good addition for tech-savvy individuals but comes at an undisclosed additional cost.</li> <li>• The operational elements appear to be eminently scalable, provided qualified personnel can be identified.</li> <li>• There is no mention of collaboration with the Alpha Clinics Network.</li> </ul>
AAWG Votes	Is the project well planned and designed?
<p><b>Yes:</b> 5 <b>No:</b> 0</p>	<ul style="list-style-type: none"> <li>• The applicant organization is adjacent to CIRM, which should facilitate communication and fine-tuning of support services offered in response to initial assessments.</li> <li>• The proposal addresses financial and language barriers explicitly. Their long experience in patient support program creation is evident in this proposal. The path of the typical patient is very clearly laid out, and it would appear they are capable of handling exceptional situations routinely.</li> <li>• Demonstrated experience with CGT and rare disease support programs. Operating multiple patient support programs now.</li> <li>• The Rules Engine is designed around Office of Inspector General (OIG) standards. It is not clear if this is acceptable to CIRM.</li> <li>• The over-arching design seems appropriate but there is insufficient detail to be confident in the success of the planned activities</li> <li>• Timeline is aggressive and there may not be enough time to modify patient facing side of the technology if necessary. Proposal does not contain a detailed implementation plan.</li> </ul>
AAWG Votes	Is the project feasible?
<p><b>Yes:</b> 5 <b>No:</b> 0</p>	<ul style="list-style-type: none"> <li>• The proposal is feasible and the applicant is willing to reassess and change.</li> <li>• The depth of this proposal, coupled with named partners, and prior experience suggests great likelihood of success. The applicant has identified risks and described reasonable mitigation plans.</li> <li>• Project management infrastructure is solid.</li> </ul>



	<ul style="list-style-type: none"> <li>• Proven technology. However, the requisite balance between technology and human touch will be critical.</li> <li>• Team is small to start with, but they indicate scalability. It is unclear if the budget anticipates this scaling .</li> <li>• The timeline is unrealistic.</li> <li>• There is insufficient detail to judge feasibility in many cases.</li> <li>• The applicant notes a partnership with an "industry-leading travel logistics provider", but the partner was not identified and so their capabilities cannot be assessed. The applicant has numerous offices nationwide, providing redundancy and a way to ensure continued operations and patient services even in the face of (for example) a natural disaster.</li> </ul>
<p><b>AAWG Votes</b></p>	<p><b>Does the project uphold principles of Diversity, Equity, and Inclusion (DEI)?</b></p>
<p><b>Yes:</b> 4 <b>No:</b> 1</p>	<ul style="list-style-type: none"> <li>• The applicant organization is one of many organizations whose purpose is to assist organizations with diverse groups of people. The applicant partners with purveyors of many needed services (financial; food; travel and housing) in a fairly comprehensive way. There are advantages of using a debit card approach or other means of reducing out-of-pocket up-front expenses.</li> <li>• Cultural training for all staff. Participates in Professional Diversity Network which aligns job seekers to corporations with commitment to DEI. Participates in National Organization for Rare Diseases.</li> <li>• While the training was not described, they note training for team members on strategies to reach and communicate with underserved communities</li> <li>• Extensive language support and commitment to bring appropriate individuals with training in medical terminology into discussions as soon as a language need is identified.</li> <li>• Identified project manager is new to the organization, but has a solid background in patient/customer services and marketing.</li> <li>• Commitment that one of the two onsite representatives will be bilingual in Spanish. The applicant has 24/7/365 access to interpreter services for 200 languages. When a non-English speaking participant is identified, an interpreter with medical terminology training is immediately brought into the call.</li> <li>• None of the biosketches for the leadership individuals mention any specific activities that would evidence a commitment to diversity, equity and inclusion.</li> <li>• There is insufficient specific evidence to judge whether the applicant has developed effective services, resources, and partnerships to support and facilitate study participation by underserved and disproportionately affected populations. For example, the applicant cites membership in associations that support and serve diverse populations, but does not identify them.</li> <li>• There is no specific description of the training activities intended to build cultural sensitivity.</li> <li>• An exclusive focus on technology use might be a hurdle.</li> </ul>



<b>Application #</b>	<b>INFR7-15523</b>
<b>Title</b> (as written by the applicant)	INFR7 CIRM Patient Support Program Services
<b>Project Objective</b> (as written by the applicant)	The objective of this program will be to implement a Patient Relationship Management (PRM) system to integrate all patient support activities across CIRM funded trials. This will allow us to seamlessly manage and optimize interactions across patients, clinical sites, sponsors, and CIRM.
<b>Summary</b> (as written by the applicant)	Develop and implement a best-in-class patient support program that can consistently and efficiently: <ul style="list-style-type: none"> <li>• Enhance access to CIRM funded clinical trials, particularly for underserved populations</li> <li>• Provide comprehensive support for participation throughout the trial and remove financial barriers to retention in clinical trials</li> <li>• Create a decision framework to identify resource deployment criteria and provide governance</li> <li>• Generate positive impact through increasing the likelihood of meeting enrollment goals on time, realizing greater trial completion rates, and protecting California's investment in CIRM</li> </ul>
<b>Statement of Benefit to California</b> (as written by the applicant)	Our PSP can provide CIRM with consistently and efficiently delivered support that is scalable across all CIRM funded trials, that generates positive impact through increasing the likelihood of meeting enrollment goals on time, realizing greater trial completion rates, and protecting California's investment in CIRM.
<b>Funds Requested</b>	\$2,485,303
<b>AAWG Recommendation</b>	Tier 2: needs improvement, could be resubmitted
<b>Process Vote</b>	All AAWG 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 AAWG."  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: 2

Up to 11 members of the AAWG score each application. The final score for an application is the majority score of all of the individual member scores. If there is no majority score, the final score is 2. Additional parameters related to the score are shown below.

<b>Highest</b>	2
<b>Lowest</b>	3
<b>Count</b>	12
<b>Votes for Tier 1</b>	0
<b>Votes for Tier 2</b>	9
<b>Votes for Tier 3</b>	3

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- A score of "3" means that the application is sufficiently flawed that it does not warrant funding.

## 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 AAWG 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><b>AAWG Votes</b></p>	<p><b>Does the application offer a meaningful value proposition to improve access and retention to CIRM-funded clinical trials through its proposed patient support services?</b></p>
<p><b>Yes:</b> 5 <b>No:</b> 1</p>	<ul style="list-style-type: none"> <li>• The proposal presents a reasonable approach to a meaningful patient support program. Demonstrates success at patient retention programs in the past.</li> <li>• Technical strength a plus and past experience with CIRM.</li> <li>• Yes. However, previous experience with CIRM was challenging. So, while on paper it looks great, previous experience doesn't support that.</li> <li>• Implementation of reimbursement services is delayed and will impact patients.</li> <li>• Needs improvement in clearly delineating the support that would lead to retention of patients.</li> <li>• It was not clear if they are strong with patient contact. Strong in data and technology.</li> <li>• The applicant has established relationships with clinics (including CIRM Alpha Clinics), patient advocate groups, physicians, and Academe. They reference prior CIRM-funded projects and have assisted dozens of other entities with various stages of this journey. Review of past performance in CIRM-funded projects does not inspire confidence in their ability to accomplish the goals of this project.</li> </ul>
<p><b>AAWG Votes</b></p>	<p><b>Is the project well planned and designed?</b></p>
<p><b>Yes:</b> 6 <b>No:</b> 0</p>	<ul style="list-style-type: none"> <li>• The applicant intends to use an automated eligibility determiner along with their own data management technology. They go into greater detail than other applicants in describing the Project Plan.</li> <li>• Project design and presented plan seem reasonable. However, prior vendor experience suggests that the applicant may not be fully focused on timely execution of agreed upon requirements.</li> <li>• Timeline issues were brought up during discussion.</li> <li>• Yes, but previous experience with CIRM is a concern.</li> </ul>
<p><b>AAWG Votes</b></p>	<p><b>Is the project feasible?</b></p>
<p><b>Yes:</b> 6 <b>No:</b> 0</p>	<ul style="list-style-type: none"> <li>• The applicant should deliver a successful product if everything they describe (and promise) is delivered.</li> <li>• Yes, but the implementation phase has a higher cost than anticipated considering their access to Alpha Clinics and current material from partnerships.</li> <li>• The project is feasible but could use more specifics in meeting goals.</li> <li>• Given previous challenges with this supplier, CIRM will need to tightly manage the implementation to keep them on track.</li> </ul>
<p><b>AAWG Votes</b></p>	<p><b>Does the project uphold principles of Diversity, Equity, and Inclusion (DEI)?</b></p>
<p><b>Yes:</b> 5 <b>No:</b> 1</p>	<ul style="list-style-type: none"> <li>• The applicant has a record of partnerships with the DEI leadership community. They make a strong case that they understand true barriers to care and how to reduce them.</li> <li>• Articulated training in DEI and clinical trials focusing on eliminating barriers to participation and continuation in the trials.</li> <li>• Specific experience with rare disease populations is not articulated and so of concern.</li> <li>• Yes, as much as written in the proposal. The focus on rare disease patients might be missing.</li> <li>• Reasonable discussion but more specifics are needed.</li> <li>• Needs further improvement.</li> </ul>



<b>Application #</b>	<b>INFR7-15628</b>
<b>Title</b> (as written by the applicant)	Enhancing Access and Support for Patients in Regenerative Medicine: CIRM Patient Support Program
<b>Project Objective</b> (as written by the applicant)	To improve access to regenerative medicine treatments by providing comprehensive patient navigation services, and reducing the financial burden on patients. Ultimately enhancing the well-being of patients while positioning California as a leader in the field of regenerative medicine.
<b>Summary</b> (as written by the applicant)	A comprehensive program designed to enhance patient support for individuals participating in CIRM-funded clinical trials. This center utilizes automated systems to efficiently address inbound service requests and direct patients to suitable clinical trials. The center will also facilitate reimbursements for eligible expenses related to trial participation. The program aims to not only provide vital support to participants but also promote diversity, equity, and inclusion in clinical trial access, particularly for underserved and disproportionately affected populations.
<b>Statement of Benefit to California</b> (as written by the applicant)	In collaboration with CIRM and clinical trial centers, the project positions California as a leader in regenerative medicine research, attracting talent, investments, and promoting the state's position as a hub for groundbreaking healthcare advancements.
<b>Funds Requested</b>	\$2,430,472
<b>AAWG Recommendation</b>	Tier 2: needs improvement, could be resubmitted
<b>Process Vote</b>	All AAWG 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 AAWG.”  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: 2

Up to 11 members of the AAWG score each application. The final score for an application is the majority score of all of the individual member scores. If there is no majority score, the final score is 2. Additional parameters related to the score are shown below.

<b>Highest</b>	2
<b>Lowest</b>	3
<b>Count</b>	12
<b>Votes for Tier 1</b>	0
<b>Votes for Tier 2</b>	7
<b>Votes for Tier 3</b>	5

- A score of “1” means that the application has exceptional merit and warrants funding.
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- A score of “3” means that the application is sufficiently flawed that it does not warrant funding.

## 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 AAWG 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.

<b>AAWG Votes</b>	<b>Does the application offer a meaningful value proposition to improve access and retention to CIRM-funded clinical trials through its proposed patient support services?</b>
<b>Yes:</b> 3	<ul style="list-style-type: none"> <li>• The applicant has the experience to engage patients, and their experience pertains to clinical trials.</li> </ul>



<p><b>No:</b> 2</p>	<ul style="list-style-type: none"> <li>Given the applicant's stated volume and tenure in this field, it should have the capacity to scale to whatever size is needed for this program.</li> <li>Collaboration does appear to be a strength in this proposal; although, a description of a successful program that this organization has worked on would strengthen the proposal.</li> <li>Technically, the project proposal can accomplish the development of a patient support program; however, it is hard to see how it will be patient centered. The proposal is company centered, and how they plan to connect with different community based programs or organizations to access patients is not well supported. It just notes how they will work with documented awarded CIRM grantees.</li> <li>It difficult to envision how this organization can evolve into a patient centered endeavor. For instance, their call center is 8-5 Monday to Friday. People work and do not have time to call then. No after hours or weekend access proposal noted. Also, mention of a successful platform for patients to access assumes patients have computers and internet options. Large areas of California are not adequately supported electronically to take advantage of this.</li> <li>The proposal is designed around an expense reimbursement model and does not provide a strong patient support focus.</li> <li>Deficiencies arise in many major areas that leave me disinclined to believe that applicants's proposal can accomplish its stated goals. They list no collaborators, rely on technology alone to reach and enroll diverse populations; submit a budget totally in prose; and declare the entire enterprise to be risk free.</li> </ul>
<p><b>AAWG Votes</b></p>	<p><b>Is the project well planned and designed?</b></p>
<p><b>Yes:</b> 3 <b>No:</b> 2</p>	<ul style="list-style-type: none"> <li>The verbal commitment to collaboration is clear.</li> <li>The proposal comments on successful programs to accomplish compliance. Reimbursement outcomes are projected to be timely with the applicant giving specific outcome goals there.</li> <li>They come across as well organized and experienced. That said, they were very vague.</li> <li>There appears to be sufficient planning proposed from a technical perspective. However, the proposal lacks comment on the challenges that we recognize in offering trials to a maximum of people with the condition being offered a treatment trial taking into account regional, financial, and cultural perspectives.</li> <li>The proposal states how they would establish a patient support center in a global way. It lacks discernable specifics, but perhaps that would be hard to do as a successful granted program would have to analyze situations once funded.</li> <li>The implementation timeline is very short.</li> <li>The proposed timeframe may be achievable, but no risks were identified. This raises concerns about the applicant's contingency planning.</li> <li>Proposer states that it has identified no risks associated with this project which suggest they may not understand the project at an appropriate level.</li> <li>The proposal's lack of detail in many areas raise concerns about the applicant's ability to identify or remedy new or unique challenges.</li> <li>The proposal's weaknesses include the following: the budget is descriptive only, no financial eligibility tool is identified, patients need to cover up-front costs out-of-pocket, and no partnerships are identified.</li> </ul>
<p><b>AAWG Votes</b></p>	<p><b>Is the project feasible?</b></p>
<p><b>Yes:</b> 4 <b>No:</b> 1</p>	<ul style="list-style-type: none"> <li>The applicant appears to have years of experience, seemingly in the pharmaceutical arena of patient access programs.</li> <li>The project appears to be achievable.</li> <li>Given the applicant's stated volume and tenure in this field, it should be able to perform this function, but a lack of detail in many areas raises concerns about its ability to do so completely or on time.</li> <li>The project is feasible, and they have a track record of delivery. However, while their budget was overall reasonable, it was not clear how things would be funded, particularly training. They did not appear to have passion or a strong drive to win the business based on the effort put into the proposal.</li> <li>The team seems pretty limited to me for such a big program. One does not get the picture of staffing as able to be easily mobile if needed.</li> <li>The bold statement that they perceive no risk or threat to the implementation of this Patient Support Program nor to its success reaching its goals suggests a naivete that may be grounded in the more routine activities they are primarily involved in. There is no mention of delays in development, launch, coordination, staffing, etc.</li> </ul>
<p><b>AAWG Votes</b></p>	<p><b>Does the project uphold principles of Diversity, Equity, and Inclusion (DEI)?</b></p>



<p><b>Yes:</b> 1 <b>No:</b> 4</p>	<ul style="list-style-type: none"><li>• Even though the applicant stated over 10 yrs of experience in the pharmaceutical field, there were no examples of what they have accomplished in their existence.</li><li>• There is scant evidence of expanding their focus on diversity to patient populations, especially with respect to lowering barriers to participation among diverse groups.</li><li>• It seems this was a major miss even when they were asked about it.</li><li>• Virtually no information was provided about DEI.</li><li>• They seemed completely tone deaf to this issue, a top priority for CIRM</li></ul>
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<b>Application #</b>	<b>INFR7-15487</b>
<b>Title</b> (as written by the applicant)	CIRM Patient Support Program (PSP)
<b>Project Objective</b> (as written by the applicant)	To significantly enhance accessibility of CIRM-funded clinical trials especially for underserved patients by addressing the financial and logistical challenges of trial-related expenses; ultimately increasing enrollment and adherence and safeguarding the investment in regenerative medicine research.
<b>Summary</b> (as written by the applicant)	Our objective for this PSP is to ensure the CIRM granting committee has completely accurate and thorough information regarding the expertise of our organization in providing patient support services for the cell & gene therapy patient population. The PSP we have designed aims to significantly enhance the accessibility of CIRM-funded clinical trials, particularly for underserved populations, by addressing financial and logistical challenges faced by patients and families during enrollment and participation in cell and gene therapy trials. We have put forth and designed the strategies outlined in this proposal to meet and exceed the required operational activities as defined by CIRM and in compliance with all state and federal regulations, demonstrating a deep understanding and experience in delivering the necessary support to patients and their support networks. Our goal is to establish consistent, efficient, and reliable access to resources and support for all patients participating in CIRM-funded trials, ultimately increasing trial enrollment and adherence, and safeguarding the investment in regenerative medicine research. The structure of the PSP will entail: Maintaining a Patient Support Services Center; Assessing Patient/Financial Eligibility; Implementing/Managing a Process to Provide Reimbursement for Eligible Trial Participation Expenses; Maintaining Accounting and Assurance of Non-duplication of Permitted Reimbursements. The PSP will assist all patient applicants by answering questions and directing them to appropriate CIRM-funded clinical trials, will assess patients/family eligibility and their need for financial support for permitted reimbursement services. We will develop and implement business rules, operating procedures and process flows to manage PSP processes and to establish the guidelines for using PAF funds for eligible clinical trial participation expenses. We will develop educational materials for use by patients, trial sponsors and sites regarding the PSP and how the program works in conjunction with trial site processes. We will establish and implement an accounting process for confirming/validating reimbursements that are not duplicative with any provided by individual sponsor's sites. Our team will manage all inquiries and provide individualized support and education to callers during normal business hours of operation Monday-Friday, 8am-5pm PT excluding California State holidays. We will continually coordinate and communicate with the sponsors/trial sites as to patients referred and reimbursements - to not duplicate reimbursements. Internet accessible standard and customized reports will be developed for the CIRM team, sponsors, and sites. Once operational, program monitoring, trend analysis and surveying will occur to identify any gaps and opportunities for additional services.
<b>Statement of Benefit to California</b> (as written by the applicant)	Benefits will extend to healthcare, equity, the economy, research, and quality of life, positioning the state as a pioneer in regenerative medicine; residents will have access to the most advanced therapies, healthcare equity, and reach/support for underserved populations. The PSP will support economic growth of the regenerative medicine sector; attract scientific/healthcare talent through continued growth as a hub for medical innovation and improve overall quality of life for Californians.
<b>Funds Requested</b>	\$2,500,000
<b>AAWG Recommendation</b>	Tier 2: needs improvement, could be resubmitted
<b>Process Vote</b>	All AAWG 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 AAWG."  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: 2

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<b>Highest</b>	2
<b>Lowest</b>	3
<b>Count</b>	13
<b>Votes for Tier 1</b>	0
<b>Votes for Tier 2</b>	7
<b>Votes for Tier 3</b>	6

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- A score of “3” means that the application is sufficiently flawed that it does not warrant funding.

## Key Questions and Comments

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<b>AAWG Votes</b>	<b>Does the application offer a meaningful value proposition to improve access and retention to CIRM-funded clinical trials through its proposed patient support services?</b>
<b>Yes:</b> 1 <b>No:</b> 5	<ul style="list-style-type: none"> <li>• The applicant team is technically able to do this project. They have substantial experience in developing and launching patient support programs for clinical trials.</li> <li>• The strengths of this application are the utilization of state-of-the-art cloud-based technologies and the applicant's communication with clinics running trials.</li> <li>• The application, overall, lacks needed specifics. A key weakness is limited description of the actual in-person activities of the call center. These should be fleshed out. The call center for CIRM PSP must address and support patients' needs to overcome barriers to enrollment and retention.</li> <li>• The program described focuses on technological and accounting aspects of qualification. This is based on a brief credit check. It is unclear why this is an appropriate approach given CIRM's goals to achieve personalized support.</li> <li>• The proposal used general terms rather than specific descriptions of the proposed services, and focused on technology rather than people. CIRM's PSP must offer a personal touch to trial participants.</li> <li>• The applicant has not clearly articulated a plan to support diverse access to clinical trials.</li> </ul>
<b>AAWG Votes</b>	<b>Is the project well planned and designed?</b>
<b>Yes:</b> 2 <b>No:</b> 4	<ul style="list-style-type: none"> <li>• Overall, yes, but challenges in enrollment of participants need to be further fleshed out for proper evaluation.</li> <li>• The technical components of the application are well-described. There are weaknesses in how the applicant will address technical challenges that patients may have in using their platforms. A plan to provide a balanced approach with robust human engagement alongside the technical platforms would strengthen the application.</li> <li>• The applicant's risk mitigation plans address their ability to manage uncertainty.</li> <li>• The budget description does not offer adequate breakdown of costs.</li> <li>• There is limited recognition of the unique problems of poverty and diversity. For example, there is no description of support other than reimbursement.</li> <li>• The proposal does not describe a clear plan of partnership with CIRM.</li> </ul>
<b>AAWG Votes</b>	<b>Is the project feasible?</b>
<b>Yes:</b> 4	<ul style="list-style-type: none"> <li>• The applicant discusses their history of successes; CIRM staff would need to assess if the timeline and goals are feasible.</li> </ul>



<p><b>No:</b> 2</p>	<ul style="list-style-type: none"> <li>• Technical feasibility is clear. The staff and strategies needed to deal with socialization of the program - direct family/patient engagement that often is needed for participants with significant health complexities and illnesses - is a weakness that will need to be addressed with greater clarity.</li> <li>• Biographies are impressive, but there are no job descriptions associated with Key Personnel.</li> <li>• Use of general terms in their proposal raises questions on feasibility. However, specific details around patient transportation and other support were also mentioned.</li> <li>• Besides boilerplate language, there is no description. It is unclear that there is any appreciation of what Alpha Clinics provide.</li> </ul>
<p><b>AAWG Votes</b></p>	<p><b>Does the project uphold principles of Diversity, Equity, and Inclusion (DEI)?</b></p>
<p><b>Yes:</b> 2 <b>No:</b> 4</p>	<ul style="list-style-type: none"> <li>• DEI issues are addressed at a reasonable level, the applicant should better describe how they will support diverse participation in the program and/or in CIRM-funded trials.</li> </ul>