

# Real Life™

CIRM Access and Affordability Working Group  
Patient Assistance Program Update  
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Aug 2nd, 2022

**CIRM**  
CALIFORNIA'S STEM CELL AGENCY

The purpose of this presentation is to follow up on the Patient Assistance Program PSP presented on June 21<sup>st</sup> 2022, provide an update on our gap analysis and introduction to a draft concept plan.



## Year 1 Discovery

- Determine Model
- Deploy gap analysis
- Implement basic services
- Create standard metric & monitor outcomes measures



## Year 2 Scale 1

- Operationalize services and finances
- Metrics tracking and report to AAWG
- On-going gap analysis



## Year 3 Scale 2

- Scale based on additional patient needs
- Metrics tracking and report to AAWG
- Internal Audit



## Year 4 Expansion

- On-going operation of suite of patient support services for clinical trials and where applicable, CIRM-funded commercially approved treatments and therapies



## Year 5 Assessment

- Continue suite of services
- Provide detailed report to AAWG and ICOC on program impact for California patients



INFORMATIONAL

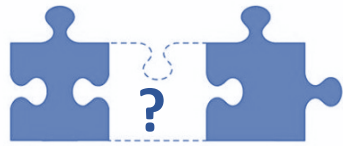
LOGISTICAL COORDINATION

FINANCIAL



The Patient Assistance Fund will be deployed to cover uncovered costs

**GAP Analysis**



Inform RFP



**Development of RFP for Patient Support Program**

Define Requirements

Detail the Key Elements

Finalize RFP

Analyze Response

Recommendations

CIRM will continue gap analysis utilizing existing Administrative funds (2022-2023 budget)

The results of the gap analysis will inform next steps and future RFPs to develop:

- Ensures regulatory compliance and avoids duplicated cost
- Refine or expand scope of patient costs covered by the Patient Assistance Fund
- Ensure consistency and alignment with other CIRM's programs
- Optimal compatibility with CIRM's infrastructure programs (Alpha Clinics and future Community Care Centers of Excellence)

Establish a Patient Support Program (PSP) with financial and logistical support to patients being evaluated or enrolled in CIRM-supported clinical trials with the aim of improving access, identification, enrollment, and retention of patients with an emphasis on underserved populations.

To achieve these aims, CIRM will offer a contract through a competitive request for proposal (RFP).

Applicants for the PSP will be required to provide an application describing their:

- Call center operations and internal capabilities and technology
- Patient navigation capacities
- Reimbursement experience for clinical research / trial participants
- Real-time reporting capabilities
- Other scalable patient services



○ Travel expenses

○ Accommodation

○ Meals

○ Childcare

○ Out-of-pocket healthcare expenses

○ Ancillary healthcare expenses, e.g., post-administration monitoring

○ Other Medical Expenses





For-profit and not-for-profit organizations providing a full suite of patient support services to meet the defined needs of the CIRM Patient Assistance Program.

Applicants must be able to initiate services within 120 days of the final contract.

Each applicant must have an appropriate California operating license(s).

All applicants must provide a robust track record of patient support services and activities and be in good regulatory standing.

Applicants must also have sophisticated data and technology services with multiple back-up capabilities.

### Service provision, vendor/call center measure and other metrics including:

- Financial assistance services demographics and utilization
  - Non-covered costs or services
  - Logistics/travel
- Alpha Clinic and future Community Center referral and satisfaction
- Program dashboard
- Quality evaluation measures of case managers
- Clinical trial recruitment and retention scores
- Patient satisfaction surveys

**CIRM has allocated \$15.6 million over 5 years for direct patient support:**

- \$600,000 in 2022-23
- \$2 million in 2023-24
- \$3 million in 2024-25
- \$5 million in 2024-25 and 2025-26

The entire \$15.6 million will be allocated to patient support.

Administration and operational costs of service contract will be allocated from CIRM's administration budget (assume it will be <\$500K for 4-5 year period)

- The CIRM team will continue with a system wide Gap Analysis and finalization of Concept Plan
- If early results identify variables (logistical or financial) strongly associated with reduced opportunity for clinical trial participation, option to present immediate findings to AAWG for program acceleration
- Based on the approved Concept Plan CIRM will create an RFP for Patient Support Service
- The RFP will be posted and applications will be evaluated by CIRM
- The CIRM team will make a recommendation for top choice(s) to the AAWG