

Real Life™

CIRM Accessibility and Affordability Working Group
Patient Assistance Program Pathways
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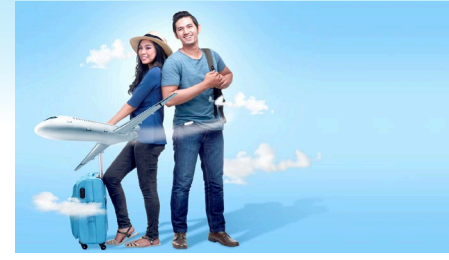
CIRM
CALIFORNIA'S STEM CELL AGENCY

- The purpose of this presentation is to follow up on the Patient Assistance Program presented on May 17th
- To present a lead option based on AAWG comments that will address logistical and financial bottlenecks observed in cell and gene therapies
- Align on a concept plan to present to the ICOC on September 29th, or earlier

- Cell and gene therapy trials are uniquely demanding on patients and require additional support beyond traditional clinical trials (Alliance for Regenerative Medicine Meeting, Washington DC, June 14, 2022)
- AMA House of Delegates Approves ASCO-Backed Resolutions on Ancillary Clinical Trial Costs (June 10 – 15, 2022)
- New Patient Assistance Programs (for profit and non-profit) emerged to address financial bottlenecks associated with cell and gene therapy trials
- Professional services are now offering a suite of services while deploying “community patient navigators” to rural communities
- Large Digital Health movement to improve diversity, equity and inclusion in clinical trials



- Travel expenses
- Accommodation
- Meals
- Childcare
- Out-of-pocket healthcare expenses
- Ancillary healthcare expenses, e.g., post-administration monitoring
- *Commercial Co-Pay assistance



* Support for transitioning patients to commercially approved products

- *Vital to provide patient assistance that covers rare conditions; recruits outside academic model, and monitors metrics*
- *A full Support Service with patient coordinated care will address “headwinds” [in regenerative trials]*
- *Community Care Centers of Excellence (CCCE) could address cultural, social and educational barriers. Patient Support could address financial and logistical bottlenecks*
- *Consider additional financial support for all grant/awardees through Affordability and Accessibility Working Group (AAWG)*
- *Update MediCal physician reimbursement to improve accessibility and affordability, if not, it will be difficult to adopt new regenerative medicine treatments for teaching hospitals*
- *Provide: 1) Financial support; 2) Care Coordination to address patient’s overall holistic needs during study; 3) Health Benefits Coordination to address headwinds from insurance coverage (e.g.. patient care outside of institutions, coverage delay in, or lack of coverage discourages people from enrolling. Consider all of these in a request for proposal (RFP)*
- *Focus on Medicare and uninsured patients*
- *Address financial constraints/resources by Alpha Clinics and then Community Care Centers of Excellence*

- Open RFP to profit, non-profit, and patient advocacy organizations
- High-touch, single point of contact with centrally managed content
- Focus on financial services that directly support patient participations in CIRM trials
- Recommendations on financial categories and limits
- Experienced Patient Navigators to consider patient and caregiver needs
- Financial support for all insurance types - specific focus on Medicare, uninsured, underinsured
- Expertise in rare diseases
- Technology enabled for data and analytics tracking/outcomes
- Cultural adaptation and translation
- Site of care coordination and ability to complement Alpha Clinics and Community Care Centers of Excellence



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 a 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