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Vice President, Medical Affairs and Policy
Update on CCCE and Introduction to Proposed Roadmap on
Access and Affordability
May 31, 2023







- An Introduction to the Proposed "Roadmap for Access and Affordability"
- Update to Community Care Centers of Excellence (CCCE)



Proposed Roadmap to Access and Affordability



Problem Statement: There are barriers to access and affordability of Cell and Gene Therapies



Opportunity: Prop14 provides dedicated funding and the formation of the Access and Affordability Working Group (AAWG) to address these barriers



Goal: The goal of the Roadmap is to identify near- and long-term initiatives to help patients overcome barriers to access and affordability





Known Barriers to Access and Affordability







CULTURAL AND SOCIAL DETERMINANTS IMPACT CARE DELIVERY

- Lower clinical trial enrollment for minorities
- Socioeconomic status, unemployment, education
- Patient population size/geography
- Stigma of disease

INFORMATIONAL

- Limited information about disease/therapy
- Medical mistrust and misinformation about regenerative medicine
- Lack of familiarity with the administration and safety profiles of cell and gene therapies

LOGISTICAL

- Significant burden for families
- Lack of reliable transportation
- Work or childcare requirements
- Geographical limitations to approved infusion centers
- Increased operational constraints on HCP staff

COVERAGE

- Cost of regenerative medicines and insurance benefits may include high copays and lifetime benefit caps
- Restrictive coverage policies for CGT
- Lack of understanding of outcomes-based models



Key Opportunity Areas to Address Barriers





INITIATIVES THAT MITIGATE NEGATIVE SOCIAL AND CULTURAL DETERMINANTS OF HEALTH

- Expansion of Alpha Clinics
- Community Outreach and Education
- Future Community Care Centers of Excellence (CCCE)
- Community Partners

PROGRAMS TO ADDRESS INFORMATIONAL BARRIERS

- Patient Support Program
- Integration with Alpha Clinics, CCCE, and Community Partners

PROGRAMS TO HELP PATIENTS NAVIGATE LOGISTICAL BARRIERS

- Patient Support Program
- Patient Assistance Fund
- Patient Navigators at the community level

SUPPORT BROAD AND FAIR COVERAGE FOR CELL AND GENE THERAPIES

- Research Real World Evidence and Health Outcomes Opportunities
- Engagement with Payers to Incentivize Broad Access and Transparent Coverage Policy
- Evaluate Outcomes-Based Payment Models



Roadmap Elements - Example



Near Term		Timeline
Expansion of Alpha Clinics (6 – 9 Clinics)	<	Jan 2023
Patient Support Program	<	RFA Posting, July 2023
Community Care Centers of Excellence	<	March 2024
Internal Initiatives		Timeline
RWE/HEOR Opportunities	<	September 2023
Payer Advisory Group Meeting	<	December 2023
Performance-Based Payment Models	<	January 2024
New Concepts		Timeline



Community Care Centers of Excellence



Update to Community Care Centers of Excellence (CCCE)



CCCE Intended to Enhance Access



- The goal is to promote access to clinical trials and potential treatments arising from CIRM-funded research
- The approach is to establish geographically diverse centers of excellence
- The Alpha Clinics Network should be leveraged to support CCCE development
 - Clinical expertise
 - Education and training curricula
 - Patient engagement





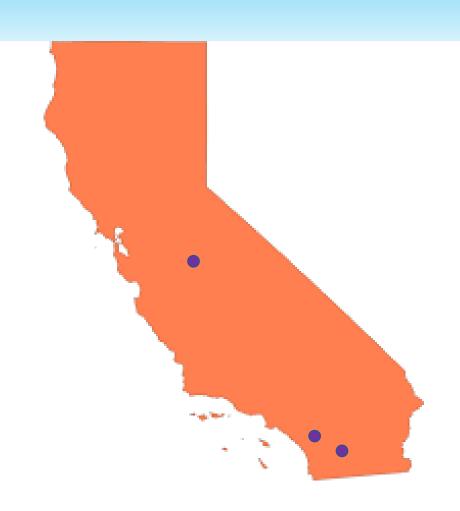
Listening Session Dates and Locations



Fresno | Clovis October 25, 2022

UC Riverside | Inland Empire January 18, 2023

Palm Desert | Coachella Valley March 6, 2023





Listening Sessions – Lessons Learned



- Clinical Capacities: Some regional medical centers are developing regenerative medicine capacity, and community providers have supported clinical research in collaboration with academic medical centers with Alpha Clinics.
- Education and Training: Education on regenerative medicine for HCP and patients. Create links with existing and emerging training and education programs.
- Access and Engagement: Community-centered patient and family engagement is highly valued. Such engagement is critical to addressing social determinants impacting participation in research.



Listening Sessions – Noteworthy Comments



- There is no center in the Central Valley right now that can offer these kinds of novel therapies. There is a real need, particularly for poor and underserved communities.
- Ask physicians to identify trusted community resources to do education and engage patients. You cannot give providers talking points to educate patients; they do not have time.
- There is a demand for access to clinical trials in her community.
 [Participant] sees many patients leaving the country to access stem cell treatments.



CCCE Process and Timeline



Needs Assessment Phase

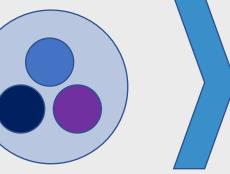
Board Review

Application Phase

Listening Sessions and Interviews

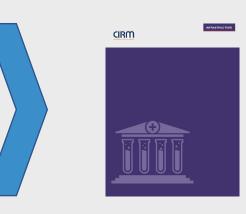


Statewide Public Workshop



Deliver
Real World
Solutions

Real
Life



- Central Valley
- Inland Empire
- Coachella Valley
- Sacramento and Virtual

- Draft Concept
- AAWG
- ScienceSubcommittee
- ICOC

- Posting of RFA
- Webinar
- Receive Applications

Oct 22 – Mar 23

June 22nd, 2023

Sept - Dec 2023

Early 2024





Thank you, and Questions