

Real Life™

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Update on CCCE and Introduction to Proposed Roadmap on
Access and Affordability

May 31, 2023

CIRM
CALIFORNIA'S STEM CELL AGENCY

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

01

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



02

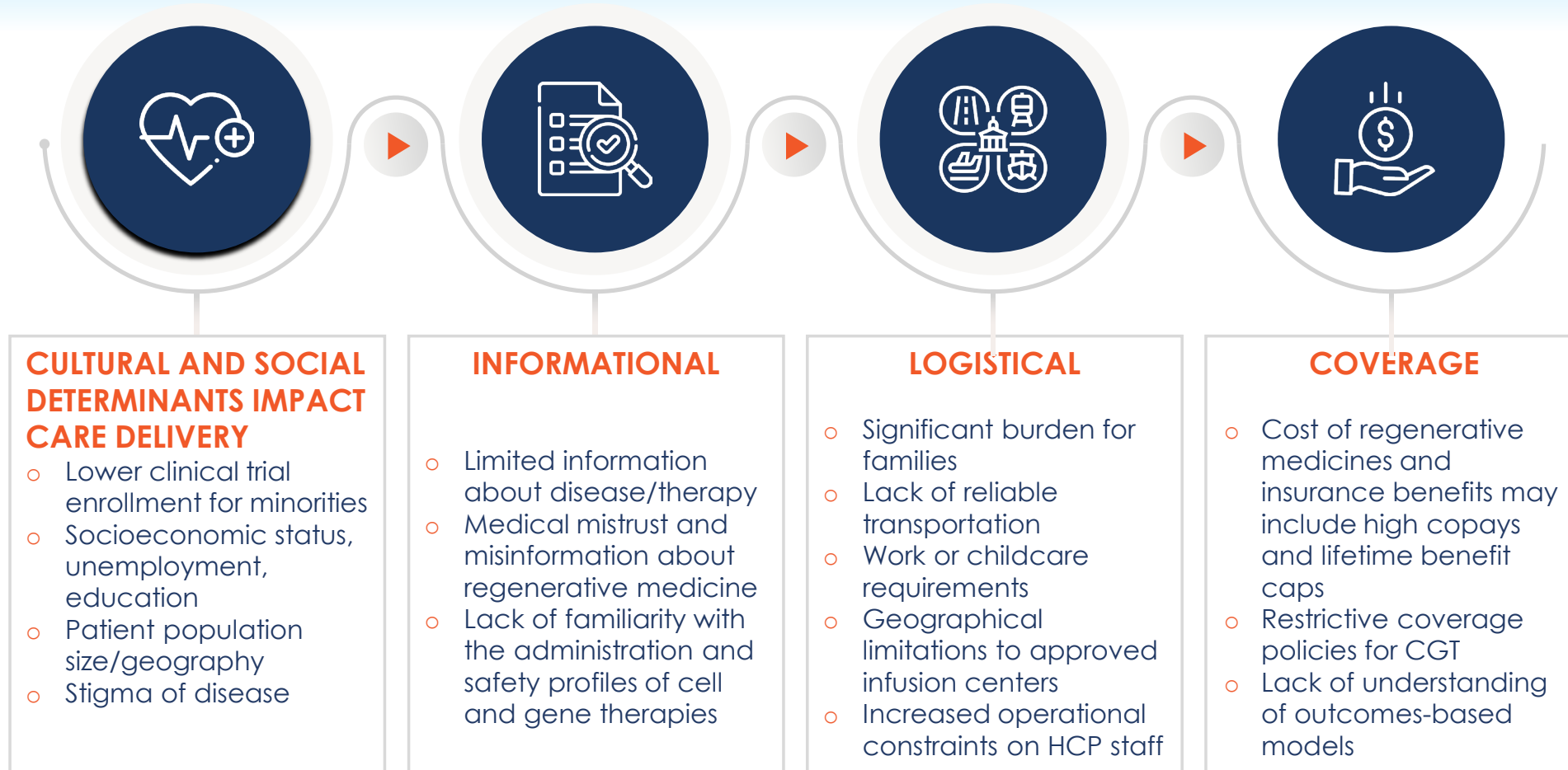
Opportunity: Prop 14 provides dedicated funding and the formation of the Access and Affordability Working Group (AAWG) to address these barriers

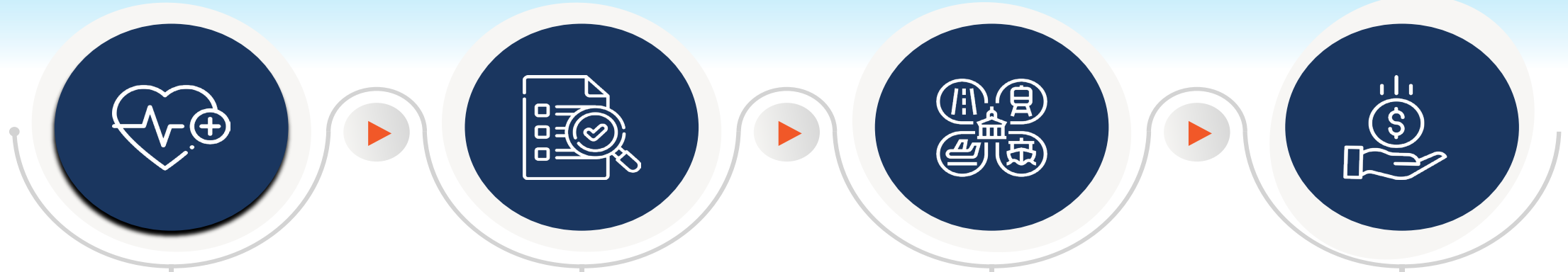


03

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







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

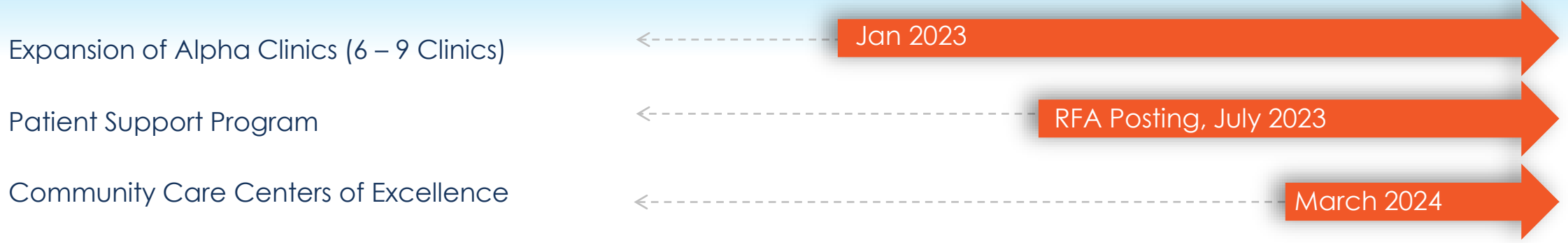
PROGRAMS TO HELP PATIENTS NAVIGATE LOGISTICAL BARRIERS

- 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

Near Term Timeline



Internal Initiatives Timeline



New Concepts Timeline

Update to Community Care Centers of Excellence (CCCE)

- 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



Fresno | Clovis October 25, 2022

UC Riverside | Inland Empire
January 18, 2023

Palm Desert | Coachella Valley
March 6, 2023



- **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.

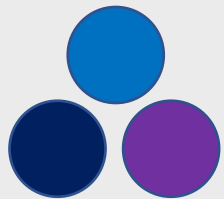
- *There is no center in the Central Valley right now that can offer these kinds of novel therapies. There is a real need, particularly for poor and underserved communities.*
- *Ask physicians to identify trusted community resources to do education and engage patients. You cannot give providers talking 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.*

Needs Assessment Phase

Board Review

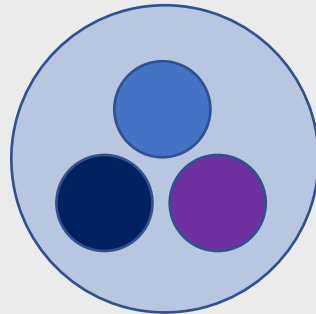
Application Phase

Listening Sessions
and Interviews



- Central Valley
- Inland Empire
- Coachella Valley

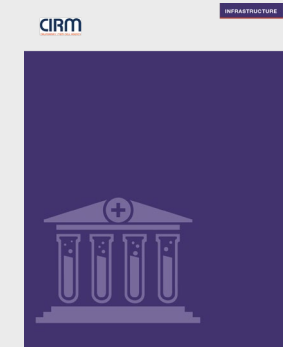
Statewide
Public Workshop



- Sacramento and Virtual



- Draft Concept
- AAWG
- Science Subcommittee
- ICOC



- Posting of RFA
- Webinar
- Receive Applications

Oct 22 – Mar 23

June 22nd, 2023

Sept - Dec 2023

Early 2024

Thank you, and Questions