Created by Prop 71 and continuing under Prop 14

Proposition 71 2004
$3B Bond Funding

CIRM
Patient-Centric, Funder, Partner, Accelerator, and De-risker for Basic, Translational, and Clinical Research Infrastructure and Education Programs

Proposition 14 2020
$5.5B Bond Funding
A Snapshot of Our Identity and Impact

- Funded >1000 projects
- Advanced stem cell research and therapy development spanning more than 75 diseases
- Funded 76 clinical trials with 3200+ patients enrolled
  - from first-in-human to pivotal phase 3
  - from common diseases to rare diseases
  - demonstrated that cures are possible (40 children treated with cell-gene therapy for ADA-SCID)
A Snapshot of Our Identity and Impact

- Generated **3,000 peer-reviewed publications**
- Funded **12 stem cell research facilities and 17 shared research laboratories**
- Enabled **invention** of research and translational tools
- Built the **largest iPSC research bank with >2,600 cell lines** for modeling
- Created **novel genomic datasets and bioinformatics tools** for stem cell research
A Snapshot of Our Identity and Impact

- Established **5 Alpha Stem Cell Clinics** that have accelerated execution of 100+ stem cell clinical trials
- Attained **Expedited Pathway Designation** from FDA: **15% of total RMATs**
- Supported **progression of 81 programs into therapy development** via successive CIRM awards
- Accelerated **73% of funded IND-enabling programs** to initiate clinical trials within 2 years
A Snapshot of Our Identity and Impact

• Trained **over 3,000 students and scholars** to become the future workforce of regenerative medicine

• Stimulated the CA economy with **$10.7B of gross output and 56,000 new FTE jobs** created during the 2004-2018 period

• Positioned CIRM-funded projects to **attract $18B+ of industry funding**
Mission Statement

Accelerating world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world.
The strategy for accomplishing this bold mission will leave a lasting legacy through the development of novel scientific endeavors, effective healthcare delivery models, and expanded education and training programs.
The new strategic plan is designed to **enhance**, **organize** and **interconnect** CIRM’s proven funding model to achieve the overarching goals.
Strategic Theme
CIRM will leverage collective scientific knowledge to inspire collaborative research that addresses Californians’ unmet medical needs.

5-year Strategic Goals

- **Continue funding mechanisms** through the existing pillar program, which promote the success of high-risk/high-reward approaches

- **Develop next-generation technology competency hubs**
  (One example: Shared labs*)

- **Build knowledge networks** to facilitate data sharing and to foster a culture of open science
  (Initially deployed to enable a consortium approach to CNS research**, including neuropsychiatric and neurodevelopmental disorders)

* Funding for shared labs stipulated in Prop 14

** To optimize the $1.5B investment for CNS-related programs as stipulated in Prop 14
Strategic Theme

Deliver
Real World Solutions

Real Life
CIRM will overcome critical bottlenecks to accelerate approval of therapies for all patients.

5-year Strategic Goals

• Optimize CIRM’s clinical trial funding partnership model to advance more therapies to FDA marketing approval

• Overcome manufacturing hurdles for the delivery of regenerative medicine therapies by building a public-private manufacturing partnership network

• Expand Alpha Clinics and create Community Care Centers of Excellence that support diverse patient participation in the rapidly maturing regenerative medicine landscape
Optimize CIRM’s clinical trial funding partnership model to advance more therapies to FDA marketing approval

- Integrated approach of CIRM’s Therapeutics Development Program
- Enables partnership with external stakeholders, regulators and payors
- Allows for expansion of CIRM’s Advisory Panel program to overcome hurdles to marketing approval and post-market considerations
Deliver Real World Solutions

Overcome manufacturing hurdles for the delivery of regenerative medicine therapies by building a public-private manufacturing partnership network

CIRM-Funded Academic GMP Facility Network

Industry Partners
- Manufacturing Services
- Resources
- Investment and Partnerships

- Accelerate and de-risk path to commercialization
- Advance standards and quality by design
- Build manufacturing leadership and workforce
Expand Alpha Clinics and create Community Care Centers of Excellence that support diverse patient participation in the rapidly maturing regenerative medicine landscape.

*Alpha Clinics Expansion and Community Care Centers of Excellence stipulated in Prop 14*
The Alpha Clinics Expansion

- Enable development and support of innovative clinical research models
- Increase access to clinical trials and approved treatments
- Expose basic scientists to clinical research
- Train clinical trial workforce including nurses and clinical research coordinators
- Partner with professional societies to develop regenerative medicine specialty certification/accreditation programs

The Community Care Centers

- Support patient referral, recruitment & access to regenerative medicine clinical trials
- Address the unique needs of the given community
- Leverage the offerings of the Alpha Clinics and CIRM’s academic institutions
- Expand engagement and participation of diverse communities in clinical research

Deliver Real World Solutions
Strategic Theme

Provide
Opportunity for All
CIRM will build inclusive participation opportunities for all stakeholders, from the students to the workforce to the patients.

- Build a **diverse and highly skilled workforce** to support the growing regenerative medicine economy in California
- Deliver a roadmap for **access and affordability** of regenerative medicine for all California patients
• Create multiple on-ramps to develop the next generation of leaders, scientists, clinicians & future workforce

• Incorporate training opportunities within CIRM scientific & infrastructure pillars:
  o Basic research
  o Translational & clinical research
  o Manufacturing sciences
  o Data science
  o Science communication
  o Community engagement
Summary of 5-Year Strategy

- Develop Competency Hubs
- Build Knowledge Networks
- Advance therapies to marketing approval
- Create a manufacturing partnership network
- Expand Alpha Clinics Network
- Create Community Care Centers of Excellence
- Build a diverse and highly skilled workforce
- Deliver a roadmap for access and affordability