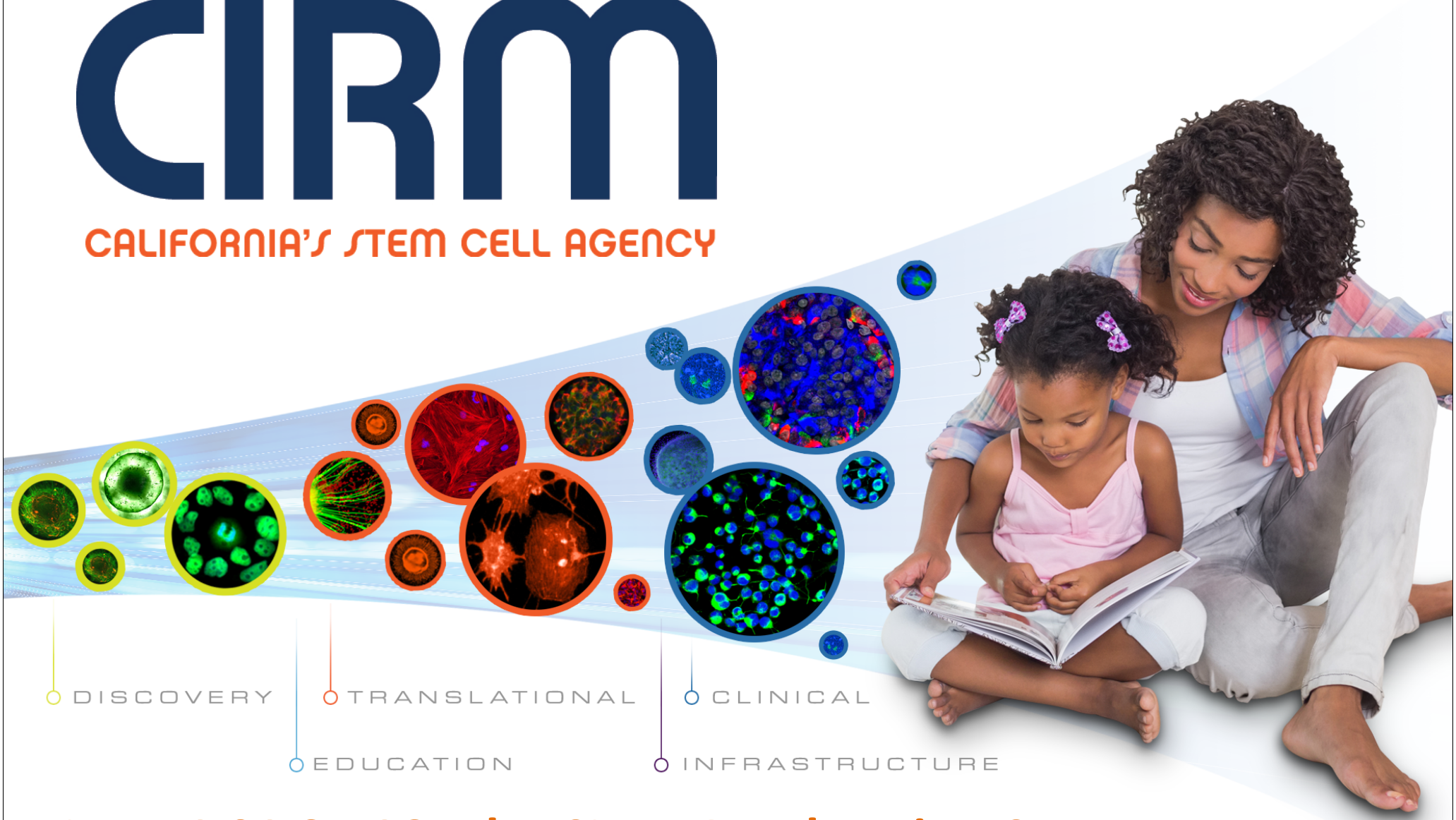
January 2016

CIRM

CALIFORNIA'S STEM CELL AGENCY

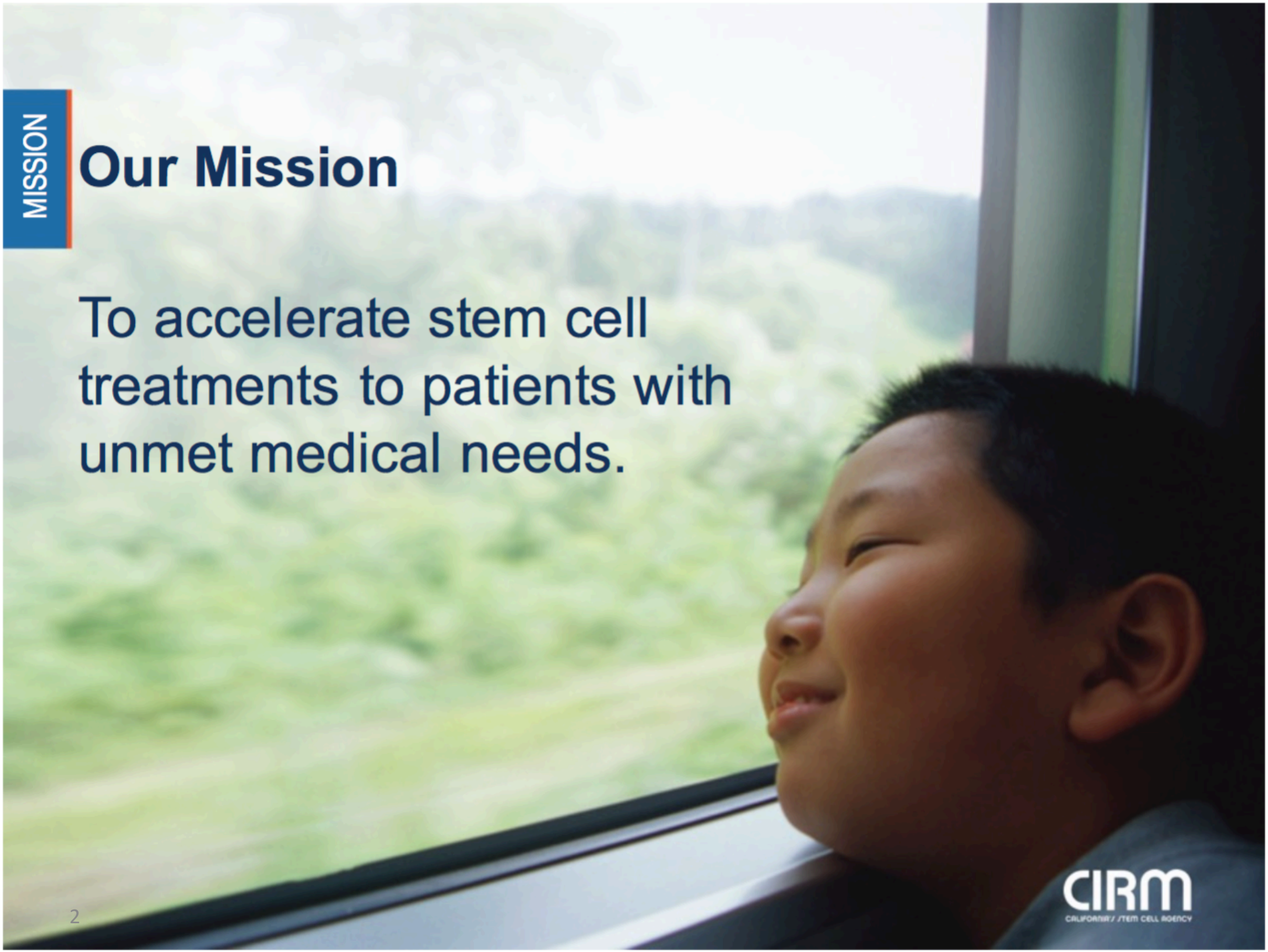


INFR 1 01.25.16: The CIRM Accelerating Center-Stem Cell Focused Clinical Research Organization

MISSION

Our Mission

To accelerate stem cell treatments to patients with unmet medical needs.



Challenges to Accelerating Stem Cell Therapies

Challenge: Moving stem cell treatments through IND-enabling studies to clinical trials takes disproportionally more time when compared to non-cellular treatments.

Solution: As integral components of CIRM's Strategic Plan, CIRM's infrastructure programs are designed to overcome the obstacles that currently slow the progress of translating stem cell research to high quality clinical trials.

see: Strategic Plan @ www.cirm.ca.gov

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CIRM Infrastructure Programs

Program	Goal	Role
Translating Center	Shorten time to clinical testing	• Process Development • IND-enabling activities
Accelerating Center	Accelerate clinical research	• Regulatory Submissions • Trial management
Alpha Clinics Network	Conduct high quality clinical trials	• Specialize in cell therapy clinical trials • Develop AVARs (Accelerating and Value Add Resources)

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Accelerating Center

- CIRM funding for a Stem Cell focused Clinical Research Organization
- Operating within California
- Up to $15 million over five years

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Accelerating Center Core Services

- Regulatory support and management services
- Clinical trial operations and management services
- Data management, biostatical and analytical services

Services will be proportional to the needs of the projects

Accelerating Center Services

- Provide core services to CIRM funded projects
- Work with the Sponsors and Translating Center to coordinate regulatory strategy
- Serve as the “lead” in assisting the Sponsor with FDA interactions and IND/IDE assembly and submission.
- Support Alpha Clinics Network operations and development of Accelerating and Value Added Resources (AVARs)

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Sustainability

- Through acquisition of unique insight and experience by supporting CIRM's projects, the AC will be positioned to develop specialized approaches and services for cell therapy trials

- The AC is expected to leverage these assets to create a sustainable platform for support of cell therapy development and stem cell clinical trials

Award Requirements

- Center Director must commit 100% effort for the first 3 yrs. of CIRM funding and no less than 80% thereafter
- Majority of AC operations involving the use of CIRM funds must take place from a CA-based facility
- The award does NOT support the cost of constructing or renovating facilities

How Will Applications be Evaluated?

- **Significance and Potential**
  - Is the proposed center likely to accelerate the progression of projects
  - Will it be sustainable
  - How strong are the offerings
- **Strength of the Plan**
  - Strength of resources
  - Does the timeline reflect the "sense of urgency" to address the stated needs
  - Will it effectively/efficiently support CIRM programs while building an overall business enterprise
- **Feasibility**
  - Personnel qualification and track record
  - Staffing & resourcing for the required services
  - Risk mitigation and contingency plans

Application Process

Online Application: End of February

Application Components:

- Program Summary
- Statement of Significance and Impact
- Project Plan
- Operational Plan
- Business & Sustainability
- Timeline
- Organizational Experience and Assets
- Core Service Capacity, Resources and Environment
- Team Organization
- Contingency Plan
- References

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Process for Funding and Timeline

Applications Due	2:00 PM PT, April 15, 2016
Grants Working Group (GWG) Review	Q2 2016
ICOC Review and Approval	Q3 2016
Award Start	Must start within 45 days of award approval

Helpful Contacts and Links

For Application Questions: GSambrano@cirm.ca.gov
For RFA Questions: Glomax@cirm.ca.gov

Strategic Plan link: www.cirm.ca.gov
Alpha Clinics link: https://www.cirm.ca.gov/patients/alpha-clinics-network/about
Translating Center link: https://www.cirm.ca.gov/sites/default/files/files/agenda/151217_Agenda_9_rev%20Translating%20Center%2011.21.15%20.pdf

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