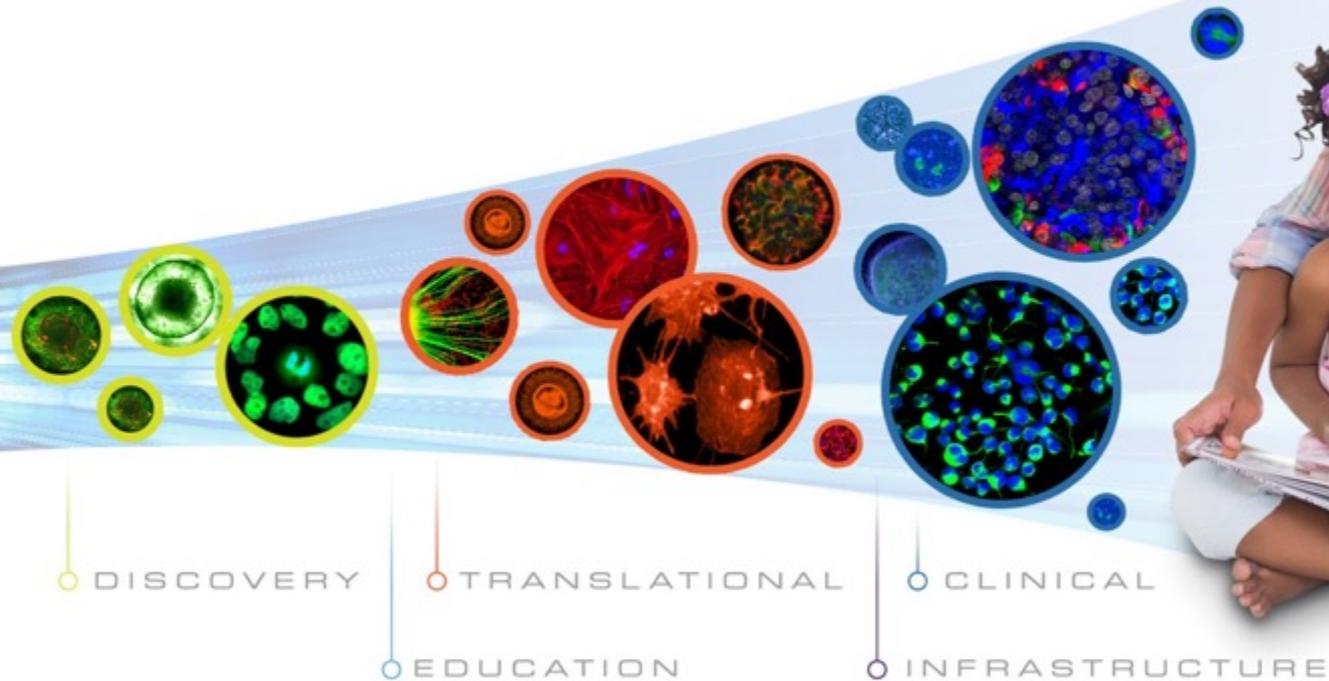


# CIRM 2.0

CALIFORNIA'S STEM CELL AGENCY



**Concept Proposal**  
**Alpha Clinics Network Expansion**  
**INFR 4**  
**Agenda Item #9**

**Maria. T. Millan, M.D.**

Vice President, Therapeutics  
California Institute for Regenerative Medicine

## Our Mission

Accelerate stem cell treatments to patients with unmet medical needs.

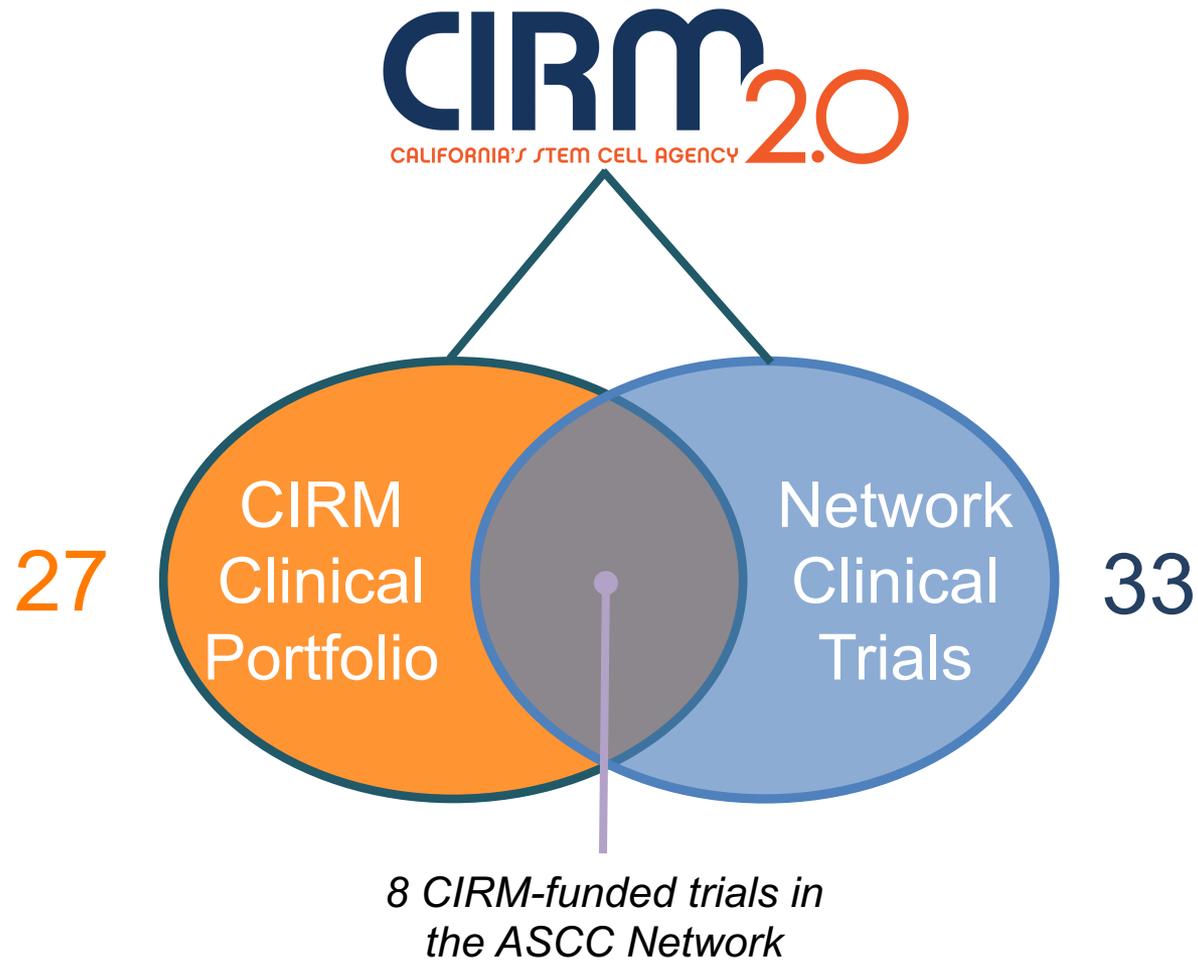
# CIRM Alpha Stem Cell Clinics Network



## Goal:

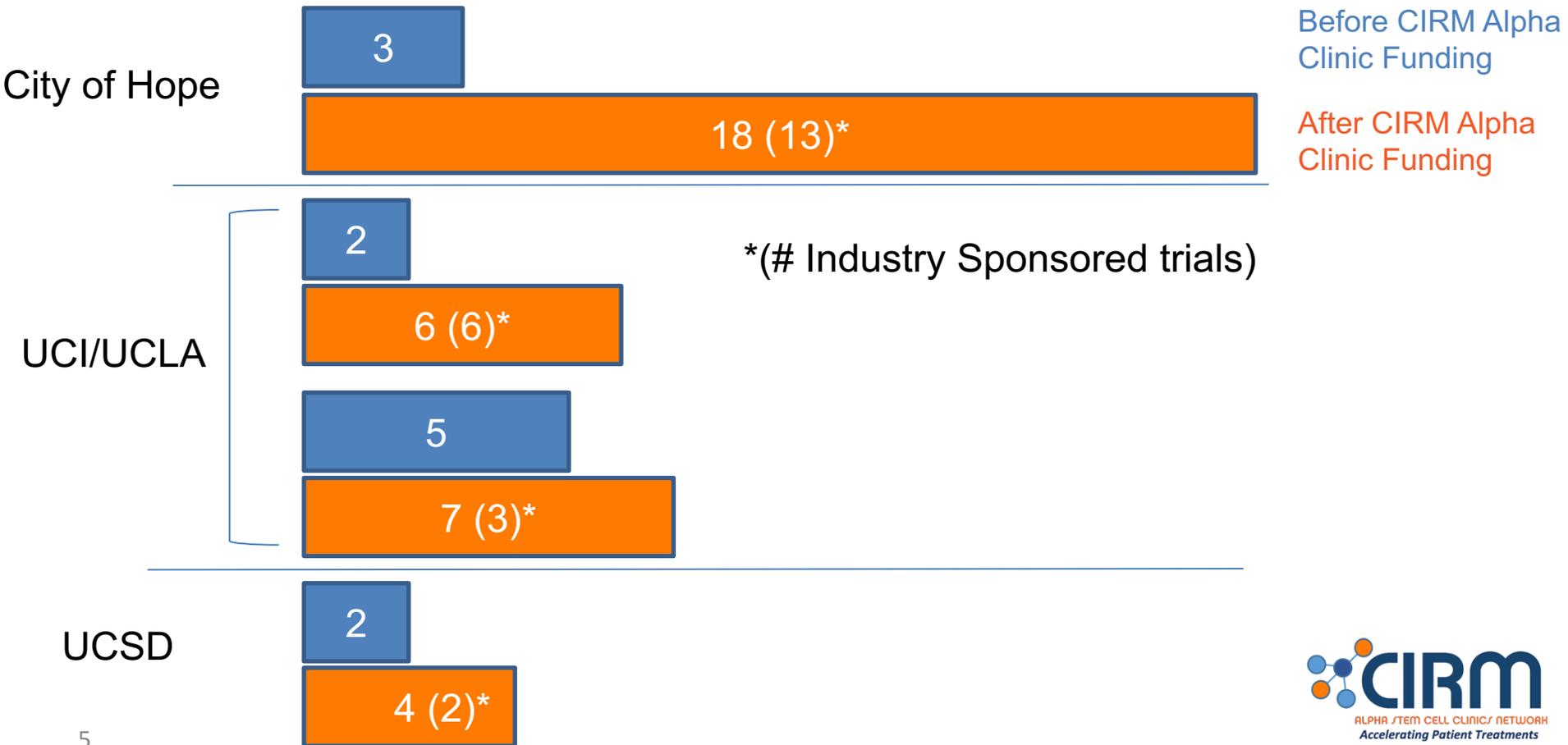
to accelerate the development and delivery of high quality stem cell clinical trials to patients

# Delivering Value to the Stem Cell Community



# The Network is a Catalyst for Expanding Clinical Trials

Before and **After** Alpha Clinic Network formation



# 33 Clinical Trials for 12 Different Indications

Indication	N
Cancer	19
HIV/AIDS	2
Immune (SCID & Granulomatous)	3
Stroke	2
Alzheimer's	1
Blindness	1
Diabetes	1
Heart Disease	1
Sickle Cell	1
Spinal Injury	1
Traumatic Brain Injury (TBI)	1



Cancer Type	N
Blood / Leukemia	6
Brain	4
Lung	3
Lymphoma	4
Ovarian	1
Sarcoma	1

# Network Acceleration Tools

- IRB Reliance allows concurrent approvals at 4 sites with a single IRB review
- Registry access to over **20 million** medical records for enrollment
- Metrics tracking to drive performance improvements
  - Time from IRB submission to IRB approval reduced by **40%**
  - Time from IRB approval to first patient enrollment reduced by **72%**

# The Network Supports Complex Trials

## ASCC Resources for unique stem cell clinical trials:

- Nursing Best Practices
- Cell handling
- Infusion/Treatment
- Patient support and informed consent tools

*The NEW ENGLAND JOURNAL of MEDICINE*

BRIEF REPORT

### Regression of Glioblastoma after Chimeric Antigen Receptor T-Cell Therapy

Christine E. Brown, Ph.D., Darya Alizadeh, Ph.D., Renate Starr, M.S.,  
Lihong Weng, M.D., Jamie R. Wagner, B.A., Araceli Naranjo, B.A.,  
Julie R. Ostberg, Ph.D., M. Suzette Blanchard, Ph.D., Julie Kilpatrick, M.S.N.,  
Jennifer Simpson, B.A., Anita Kurien, M.B.S., Saul J. Priceman, Ph.D.,  
Xiuli Wang, M.D., Ph.D., Todd L. Harshbarger, M.D., Massimo D'Apuzzo, M.D.,  
Julie A. Ressler, M.D., Michael C. Jensen, M.D., Michael E. Barish, Ph.D.,  
Mike Chen, M.D., Ph.D., Jana Portnow, M.D., Stephen J. Forman, M.D.,  
and Behnam Badie, M.D.

# Alpha Stem Cell Clinics Network Expansion Award (INFRA 4)

The objective of the Network Expansion Award is to support additional Alpha Clinic sites that will:

- Increase capacity and access to services necessary to conduct high-quality stem cell clinical trials
- Support the training and career development of physicians seeking to perform clinical trials
- Enhance the network by bringing additional assets

# Alpha Stem Cell Clinics Network Expansion Award (INFRA 4)

- Located in an Academic California Medical Center
- Demonstrate ability to perform stem cell clinical trials
- Provide services and programs:
  - ✓ Patient recruitment, education and care, serving California's diverse population.
  - ✓ Clinical trial operations and management services.
  - ✓ CIRM Alpha Clinic Fellowship Program
  - ✓ Enhance Alpha Clinics Network offerings

# Requested Award Amount and Proposed Timeline

Two awards of up to \$8.0 million each in total funding over four years

<b>Applications Due</b>	2:00 PM PT, May 15, 2017
<b>Grants Working Group (GWG) Review</b>	July 2017
<b>ICOC Review and Approval</b>	August 2017
<b>Award Start</b>	Must start within 45 days of award approval