

Beyond  
**CIRM**2.0  
CALIFORNIA'S STEM CELL AGENCY

*now it's personal*

## Strategic Plan Overview

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# Strategic Planning Purpose

## Situational Awareness



The planning process is a unique opportunity to evaluate changes and challenges in our environment since the last strategic plan was enacted in 2012 and consider implementation of new ideas or changes in course.

## Organizational Clarity



After this process, our mission will be clear, and those responsible for fulfilling it will embrace it with conviction. A clear mission leads to clear priorities and direction. These priorities will align our efforts, increasing our output and results.

## Measurable Goals



For goals to be effective, we must be able to measure our progress against them without debate or room for interpretation. With measurable goals, if we are not on track, we will be able to adjust our course in time to allow us to meet our targets. We are setting concrete, tangible goals through this process.

# Funding Runway

Current levels sufficient to last approximately 5 years



- \$2 billion awarded or spent
- \$775 million uncommitted
- \$190-200 million in new awards per year
- Estimated \$20 million in award reductions annually
- Projected NET commitment rate of \$170 million per year

# Where We Are Today



## Key insights from an honest and thorough assessment

- Historically, CIRM existed as an initiative (vs. system) based agency
- With a few exceptions, most priorities are aligned among stakeholders
- The translation stage represents a significant opportunity for CIRM to impact speed and efficiency
- Stem cells therapies continue to be disadvantaged (regulatory and commercial)
- The regulatory environment is seen as a major impediment to stem cell therapy

# Mission Confirmation

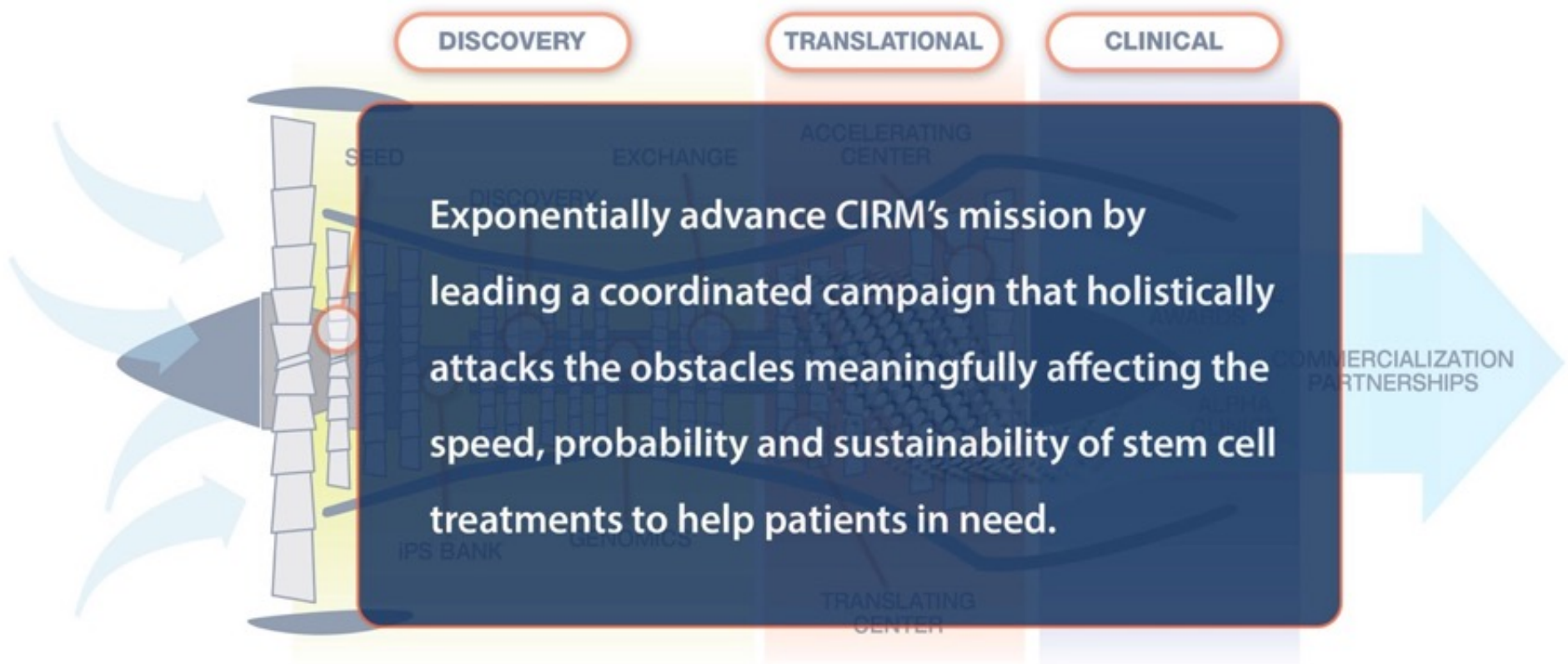
When asked, Board members and Stakeholders agree on CIRM's mission.

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



# Where We Are Going

A **bold** vision to maximize CIRM's impact





# Three Strategic Themes

Integrating the pieces will turn CIRM into a stem cell accelerating machine



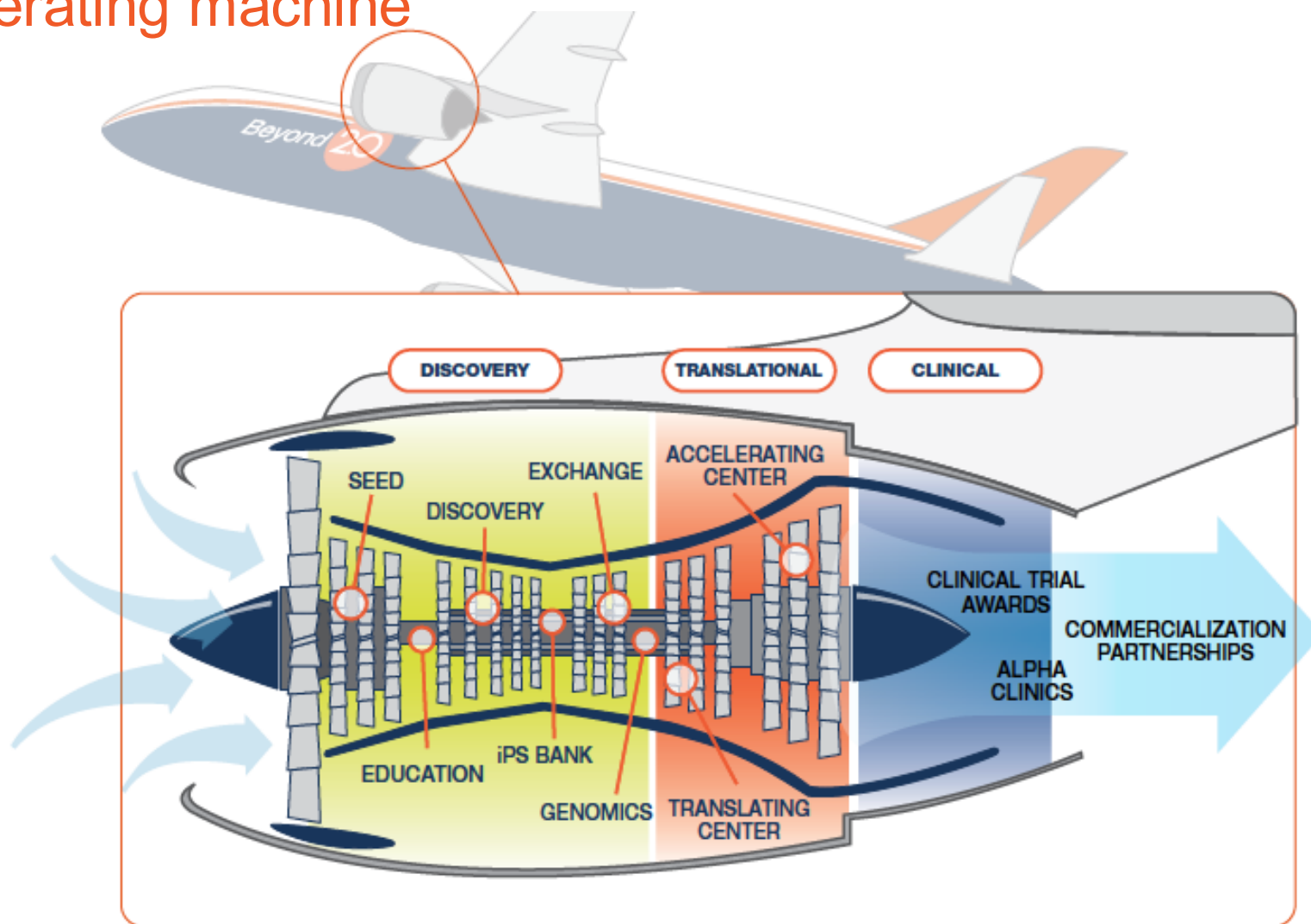


# Specific Actions



# Assembling the Parts

Integrating the pieces will turn CIRM into a stem cell accelerating machine



# Expected Results

## Major Goals



- **Discover:** Introduce 50 new therapeutic or device candidates into development.
- **Advance:** Increase projects advancing to the next stage of development by 50%.
- **Refine:** Enact a new, more efficient regulatory paradigm for cell therapies.
- **Accelerate:** Reduce the time it takes a stem cell therapy to move from discovery into a clinical trial by 50%.
- **Validate:** Add 50 new clinical trials to the CIRM portfolio, covering at least 20 unique diseases or conditions, and including at least 10 orphan and 5 pediatric indications.
- **Partner:** Pair at least 50% of our unpartnered clinical stage projects with commercial partners.

# Financial Summary

Program	2016	2017	2018	2019	2020	Total
Education	10	10	10	10	10	50
Discovery	15	50	50	35	20	170
Translation	30	45	45	40	20	180
Clinical	90	100	100	100	50	440
Infrastructure	15	15	20	0	0	50
<b>Totals</b>	<b>\$160</b>	<b>\$220</b>	<b>\$225</b>	<b>\$185</b>	<b>\$100</b>	<b>\$890</b>

Financial Figures are in Millions

## Key Financial Assumptions:

- The "engine" is anticipated to be producing maximum power by 2017.
- \$50 million previously committed by the ICOC for education (SPARK and Bridges programs) from 2016-2020.
- Translating Center estimated to cost between \$12-15 million.
- Accelerating Center estimated to cost between \$12-15 million.
- Recovery rate from canceled projects expected to be approximately 10%.

# Risks

## Key risks include but are not limited to the following

- There may be an insufficient number of meritorious therapeutic candidates to reach our goals
- There may be insufficient interest from qualified applicants to participate in key competitions
- The current limited funding of the agency could affect the ability to retain or attract personnel
- Investors may be uninterested in stem cell therapies
- The FDA may be unwilling to improve the regulatory environment

# Beyond CIRM 2.0: ALL IN

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