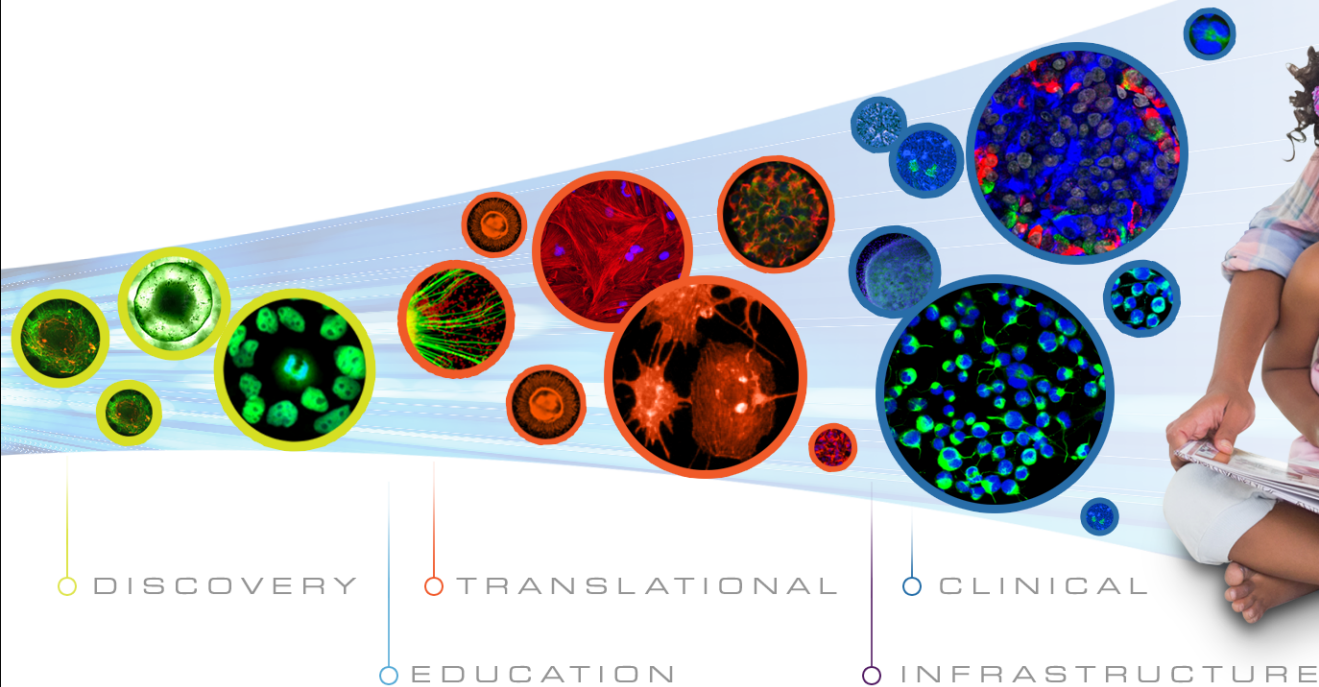


CIRM 2.0

CALIFORNIA'S STEM CELL AGENCY



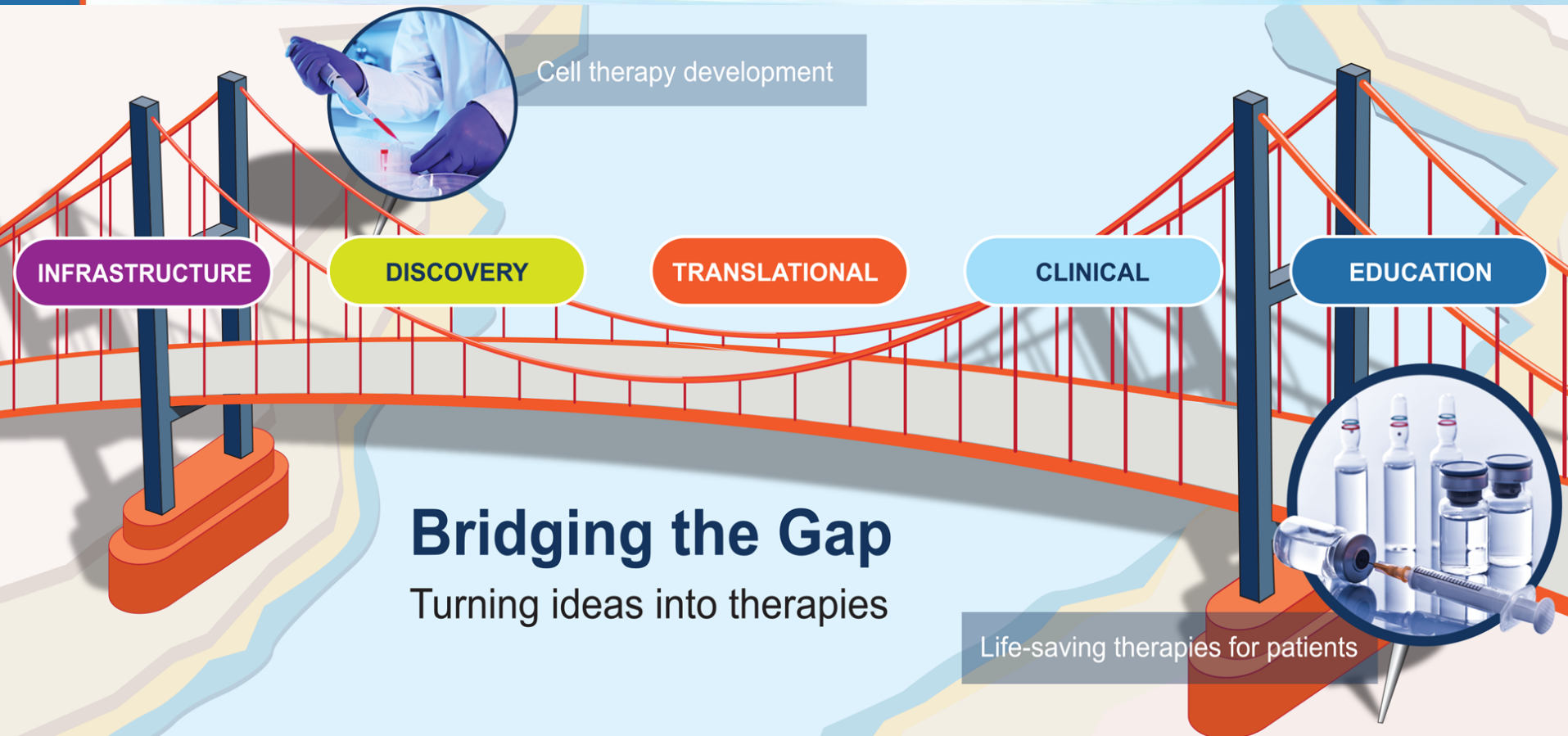
ATP3 – Award Review Process

Scott Tocher
Deputy General Counsel

Our Mission

Accelerating stem cell treatments to patients with unmet medical needs.

CIRM 2.0: Accelerating Cures



ATP3 Objectives

Accelerating Therapies through Public-Private Partnership

Engage Industry by:

- Creating an opportunity to form an entity that would aggregate CIRM's most promising technologies
 - Offers multiple “shots on goal” and increases the probability of success
 - Makes significant industry investment more attractive
- Leveraging CIRM's administrative and review infrastructure and its external team of world-class subject matter experts to promote informed insight into CIRM's portfolio of stem cell projects
- Continued CIRM funding for the development of in-licensed CIRM technologies

Private Partner (ATP3 Awardee)

- Could be an established company, a spin-off, or a new company with a team formed by Pharma, biotechnology, or by an investor
- Exceptional business plan = value creation for stakeholders
- Top-Tier leadership team
- Significant upfront investment capital
- Access to CIRM funding for in-licensed CIRM projects

ATP3 Focus – Two-fold

- 1) Identifying the best management team with the most promising strategy to succeed in commercial stem cell therapy development; and
- 2) Providing the infrastructure to review and administer the in-licensing of CIRM projects by the entity.
- THUS, a two-step review at the Grants Working Group

Step 1 – Identifying Newco – Making the Award

- The review will focus on whether the applicant is likely to accelerate CIRM-funded technologies toward commercialization, and the plausibility of the scientific approach underlying its business strategy.
 - Aggregation Strategy: a proposal outlining the strategy and scientific rationale for the types of technologies (e.g., the disease indications) or technology platforms (e.g., cell type)
 - Operational plan
 - Value Proposition
 - Likelihood the team will successfully in-license CIRM-funded technologies

Step 2 – In-Licensed Projects Review

- Once awarded by the Application Review Subcommittee of the Board, Newco will be required to expeditiously identify specific CIRM projects to in-license.
- Development milestones will be agreed to in the Research and Financing Agreement to ensure that Newco adheres to appropriate timelines for in-licensing projects.

Step 2 – In-Licensed Projects Review

- 1. Bucket 1 – Active New Projects: Active CIRM-funded projects that have been approved by the Application Review Subcommittee within the preceding 12 months will not require new GWG review (unless CIRM requests one).
- 2. Bucket 2 – Active Mature Projects: Active CIRM-funded projects approved by the Board more than 12 months earlier will require a new GWG review, limited to the question of whether the project is in good standing, e.g., has met or is on target to meet milestones, or if the project has not met milestones, has a viable path to accomplish them.
- 3. Bucket 3 – Non-CIRM or Inactive Projects: These projects will be subject to a full GWG CLIN-style review if Newco wants to use CIRM ATP3 funds – limited to \$75m.

Requested Action

- CIRM requests the Board approve the proposed process for the ATP3 program review.