

**SOMETHING  
BETTER  
THAN HOPE**

**Grants Working Group Recommendations:  
TRAN Review**

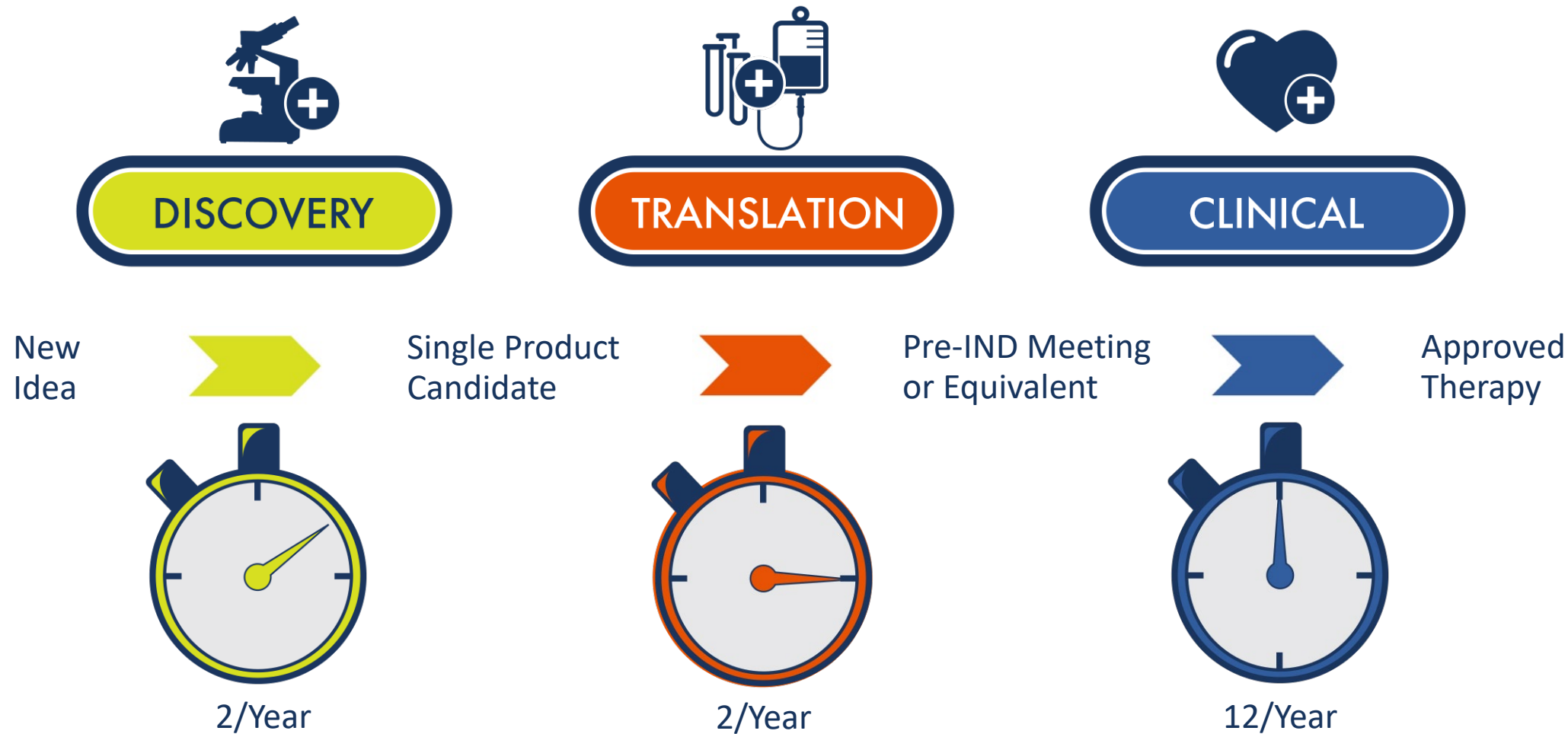
**Gil Sambrano**

Vice President  
Portfolio Development and Review

November 23, 2021

**CIRM**  
CALIFORNIA STEM CELL AGENCY

# CIRM Recurring Core Funding Opportunities for Therapy Development

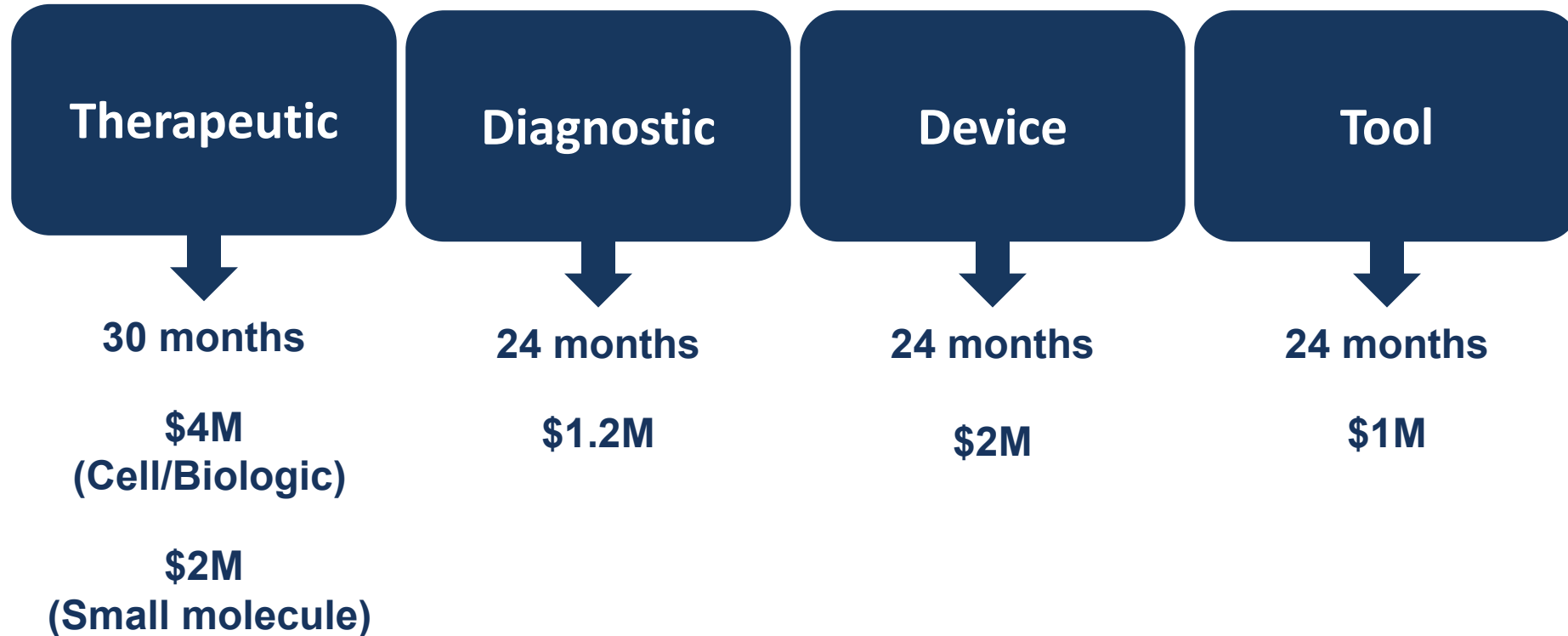


# CIRM Translational Research Program (TRAN)

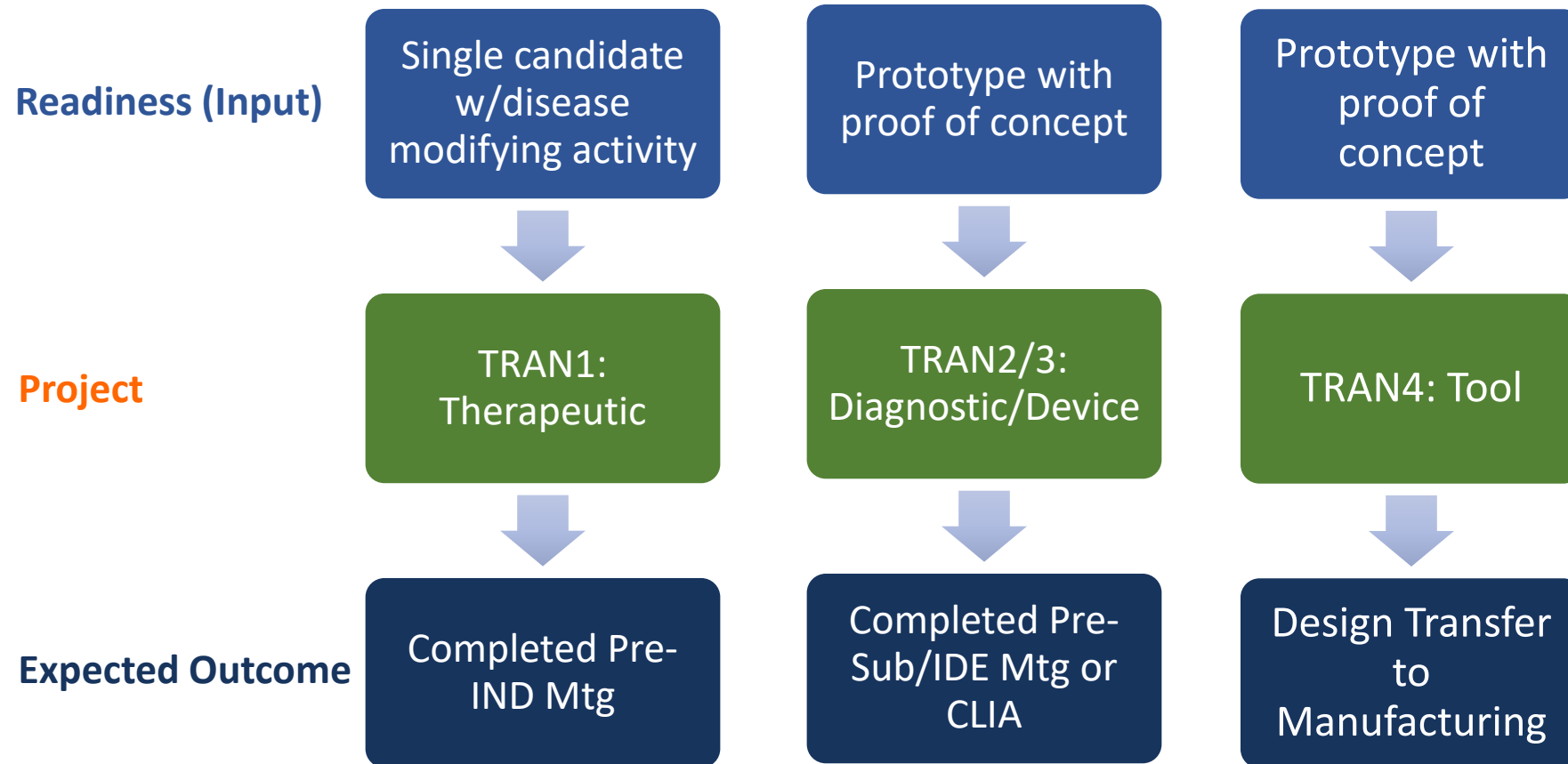
## Objective

To support promising stem cell-based projects that accelerate completion of translational stage activities necessary for advancement to clinical study or broad end use.

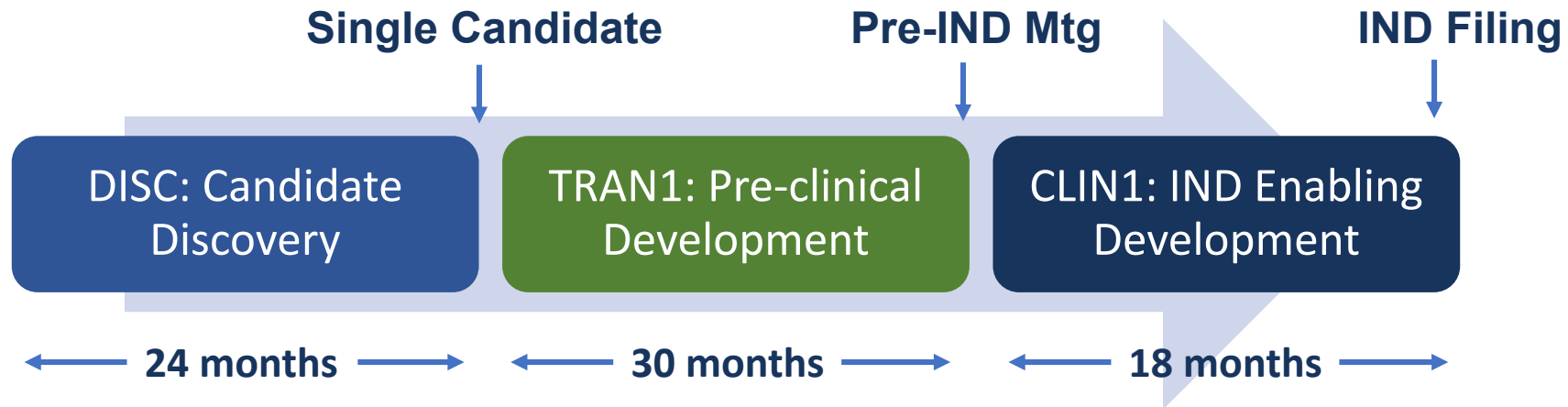
# CIRM Translational Program (TRAN)



# CIRM Translational Program (TRAN)



# Accelerating Therapeutic Development



Expected **outcomes** of TRAN1 applications:

- Pre-IND meeting conducted and formal meeting minutes forwarded to CIRM
- Pivotal IND-enabling preclinical studies protocols drafted
- GMP-compliant Master Cell Bank and Working Cell Bank established
- Clinical indication defined and draft clinical protocol synopsis developed

# Review Criteria

1. Does the project hold the necessary significance and potential for impact? (i.e., what value does it offer; is it worth doing?)
2. Is the rationale sound? (i.e., does it make sense?)
3. Is the project well planned and designed?
4. Is the project feasible? (i.e., can they do it?)
5. Does the project address the needs of the underserved?

# Addressing Needs of the Underserved:

## *GWG 5<sup>th</sup> Review Criterion*

### 5. Does the project serve the needs of underserved communities?

- Does the project plan and design adequately address and account for the influence of race, ethnicity, sex and gender diversity?
- Would the project outcomes inform the development of a product or tool that serves the unmet medical needs of the diverse California population, including underserved racial/ethnic communities?



# Scoring System

- **Score of “85-100”**

*Recommended for funding, if funds are available*

- **Score of “1-84”**

*Not recommended for funding*

Applications are scored by all scientific members of the GWG with no conflict.

The **median** of all individual GWG scores determines final score.

# GWG Recommendations

	Number of Apps	Total Applicant Request	Funds Available
<b>Recommended for funding</b> Score 85-100	10	\$40,178,744	\$52,000,000
<b>Not recommended for funding</b> Score 1-84	9		

For each award, the final award amount shall not exceed the amount approved by the ICOC Application Review Subcommittee and may be reduced contingent on CIRM's assessment of allowable costs and activities.

# Minority Reports

- Under Prop 14, any application that is not recommended for funding by the GWG, but which had 35% or more members score to fund the application must include a minority report.
- The minority report is included in the review summary and provides a brief synopsis of the opinion of reviewers that scored the application 85 or above.

# TRAN1-12907 Minority Report

Score	Num $\geq$ 85 (Fund)	Num <85 (Do not fund)	Range	Funds Requested
83	6	7	78-90	\$3,923,191

**TITLE:** Investigational New Drug (IND)-enabling studies of a wearable therapeutic device for cardiac regeneration after myocardial infarction (MI)

**DISEASE INDICATION:** Myocardial infarction

**PRODUCT TYPE:** Biologic and device combination

**APPROACH:** A biologic with cardio-regenerative effects acting on cardiac tissue progenitor cells to reduce scar formation and restore function.