

Real Life™

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Vice President Portfolio Development and Review
GWG Recommendations Translational Applications

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CIRM
CALIFORNIA'S STEM CELL AGENCY

OUR MISSION

Accelerating world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world





DISCOVERY



TRANSLATION



CLINICAL

New
Idea



Single Product
Candidate



Pre-IND or
Equivalent



Approved
Therapy

TRAN1
Therapeutic

30 months
\$4M
(Cell/Biologic)
\$2M (Drug)

TRAN2
Diagnostic

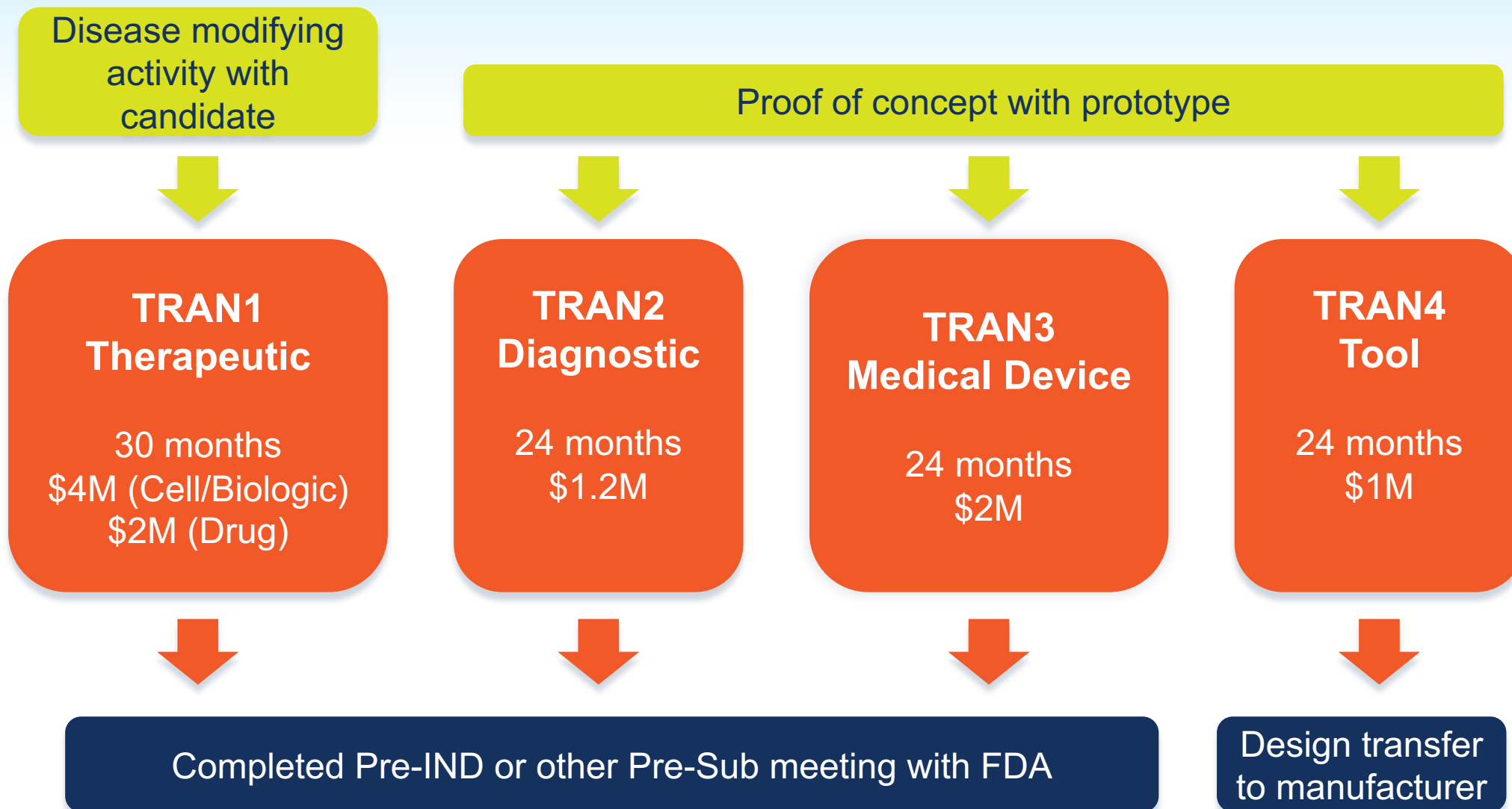
24 months
\$1.2M

TRAN3
**Medical
Device**

24 months
\$2M

TRAN4
Tool

24 months
\$1M



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 uphold principles of Diversity, Equity, and Inclusion (DEI)?

- **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.

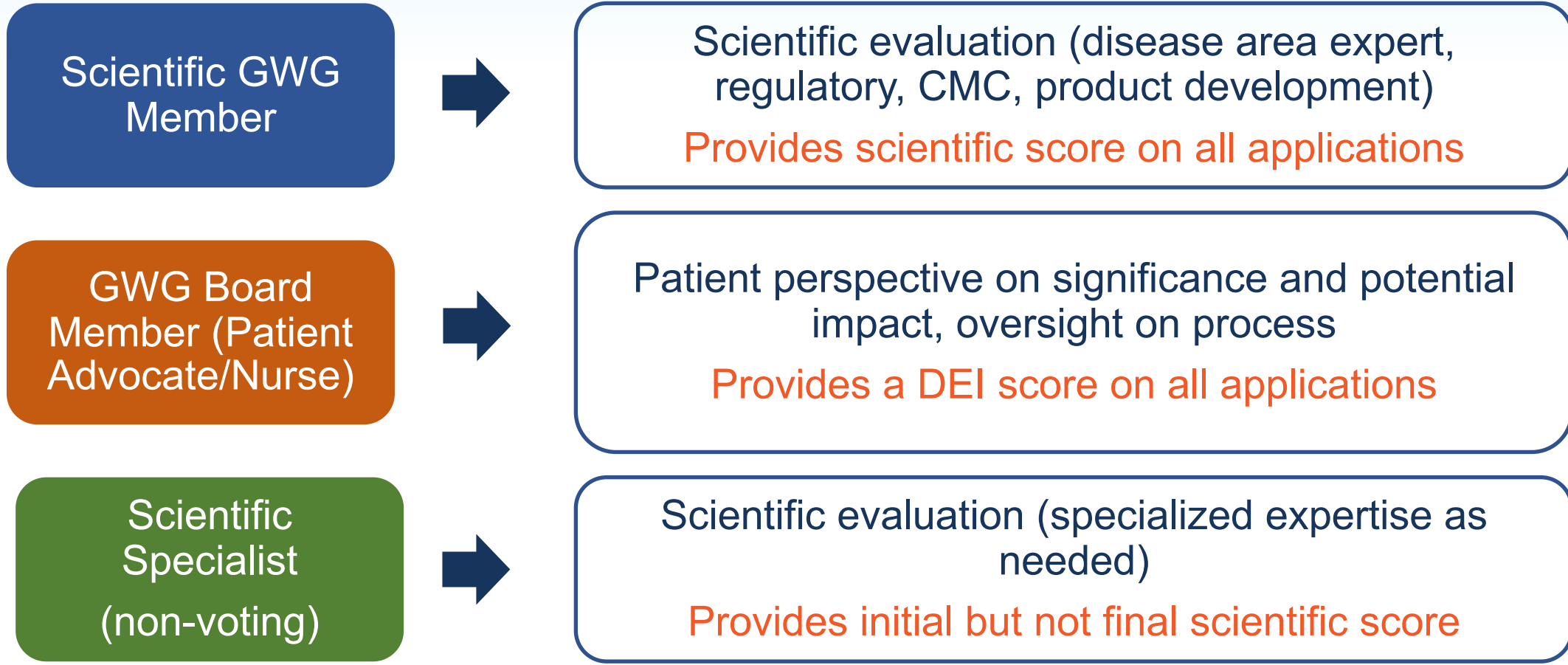
CIRM TRAN Program DEI Rubric				
CRITERIA	Score of 0 to 2 Not Responsive	Score of 3 to 5 Not Fully Responsive	Score of 6 to 8 Responsive	Score of 9 to 10 Outstanding Response
1. Product Development	Inadequate discussion on what is currently known about demographic disparities in the population that will benefit from the proposed product.	May have inadequate discussion on what is currently known about demographic disparities in the population that will benefit from the proposed product.	Adequate discussion on what is currently known about demographic disparities in the population that will benefit from the proposed product.	Strong discussion on what is currently known about demographic disparities in the population that will benefit from the proposed product.
	Planned/completed activities do not demonstrate an understanding of the potential influence of patient diversity on the safety, efficacy, and overall utility of the proposed product.	Planned/completed activities are incomplete or inadequate and may not demonstrate an understanding of the potential influence of patient diversity on the safety, efficacy, and overall utility of the proposed product.	Planned/completed activities reflect a good faith effort and have the potential to be effective in understanding the potential influence of patient diversity on the safety, efficacy, and overall utility of the proposed product.	Planned/completed activities reflect an outstanding and comprehensive effort and are likely to be effective in understanding the potential influence of patient diversity on the safety, efficacy, and overall utility of the proposed product.
	Does not address limitations, advantages and/or challenges of this project in developing a product that addresses the unmet medical needs of the diverse California population, including underserved racial/ethnic communities.	May not fully address limitations, advantages and/or challenges of this project in developing a product that addresses the unmet medical needs of the diverse California population, including underserved racial/ethnic communities.	Addresses limitations, advantages and/or challenges of this project in developing a product that addresses the unmet medical needs of the diverse California population, including underserved racial/ethnic communities.	Comprehensive discussion on limitations, advantages and/or challenges of this project in developing a product that addresses the unmet medical needs of the diverse California population, including underserved racial/ethnic communities.
2. DEI Enhancement Strategies	Has not or will not include diverse and inclusive perspectives and experience from the population that will benefit from the product, or activities proposed are not appropriate.	May not have or may not effectively or sufficiently bring diverse and inclusive perspectives and experience from the population that will benefit from the product. Activities may not match the needs of the project.	Has or will appropriately bring diverse and inclusive perspectives from the population that will benefit from the proposed product. Activities match the needs of the project.	Has or will have outstanding incorporation of diverse and inclusive perspectives from the population that will benefit from the proposed product. Activities are well matched to the needs of the project.

DEI Scores

Applications are scored for adherence to principles of DEI by all GWG Board Members with no conflict.

- **DEI Score of 9-10**
Outstanding Response
- **DEI Score of 6-8**
Responsive
- **DEI Score of 3-5**
Not Fully Responsive
- **DEI Score of 0-2**
Not Responsive

The median of all individual DEI scores determines final DEI score.



GWG Recommendations

	Number of Apps	Total Applicant Request	Funds Available
Recommended for funding Score 85-100	10	\$33,438,943	\$84,600,000
Not recommended for funding Score 1-84	20		

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.

- 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.

App Number	Title	Funds Requested	Score
TRAN1-15209	Clinical Development of Extracellular Vesicle-based Therapy for Alport Syndrome	\$5,166,326	80

The CIRM Team supports the majority position (Do Not Fund) for application **TRAN1-15209** and recommends that the applicants revise and resubmit for the next TRAN cycle.