

Grants Working Group Recommendations TRAN Review



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Vice President, Portfolio Development &
Review

ICOC/ARS Meeting

January 30, 2025

Our Mission

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



CIRM Pipeline Programs 2015-2024



Translational



TRAN1
Therapeutic
(27 apps)

Regenerative medicine-based **therapeutic candidates** (stem cell-based or genetic therapy)

TRAN2
Diagnostic
(1 app)

Diagnostics for patient screening, risk stratification, diagnosis, treatment selection or monitoring that are based on human stem cells or are critical for the development or use of a human stem cell-based or genetic therapy treatment

TRAN3
Device
(1 app)

Non-diagnostic **medical devices** critical for development or use of a human genetic or stem cell-based therapy and subject to FDA regulation under a 510(k), PMA, or BLA

TRAN4
Tool
(3 apps)

Novel **tools** for broad end use that addresses a critical bottleneck to the discovery or development of stem cell-based or gene therapy. Not subject to FDA regulation.

Translational



TRAN Readiness

TRAN Activities

TRAN Objective

**TRAN1
Therapeutic
(27 apps)**

Disease modifying activity shown with candidate

CMC, preclinical & nonclinical studies, IND-enabling plan

FDA pre-IND meeting

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

**TRAN2/3
Diagnostic/
Device
(2 apps)**

Feasibility to address unmet medical need shown with prototype

Design, manufacturing, testing, preclinical or clinical plan

FDA pre-Sub meeting or CLIA readiness

24 months
\$1.2M (Diag)
\$2M (Device)

**TRAN4
Tool
(3 apps)**

Feasibility to address bottleneck shown with prototype

Design, manufacturing, testing, commercialization plan

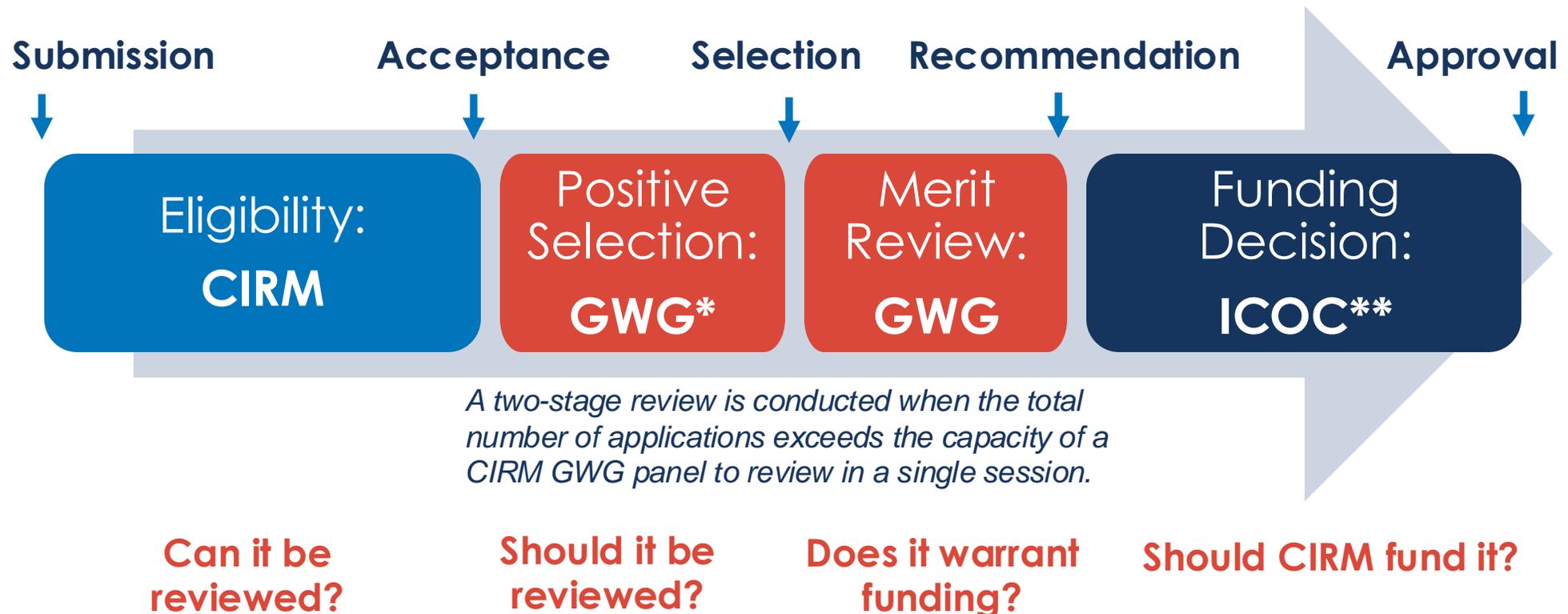
Design transfer to manufacturing

24 months
\$1M

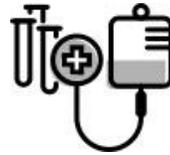
Translational



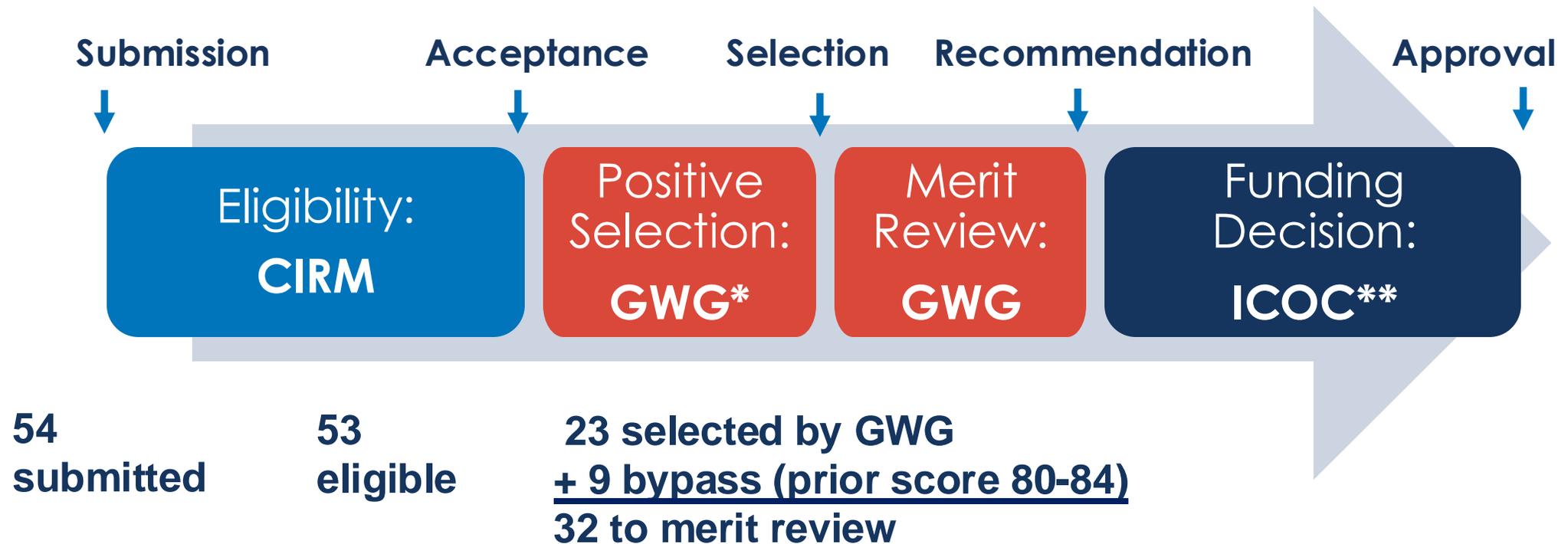
TRAN Application Review Process



Translational



TRAN Application Review Process



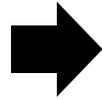
*Grants Working Group **Independent Citizens' Oversight Committee

Translational



Review Panel Roles

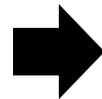
Scientific GWG
Members



Scientific evaluation based on broad subject area or
methods expertise

Enter final scores for **every** application

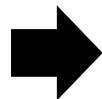
GWG Board
Members



Patient perspective on significance and potential
impact, oversight on process

Do not enter final scores; may recommend scores

Specialists



Scientific evaluation based on specialized expertise

Provide recommended scores during discussion

Translational



TRAN 1 – 100 Scoring

- Score of **85 to 100**: Application has exceptional merit and warrants funding.
- Score of **1 to 84**: Application is not recommended for funding.

Translational



TRAN Scoring Criteria

1. Does the project hold the necessary significance and potential for impact? (i.e., 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 the applicant do it?)
5. Does the project uphold principles of diversity, equity and inclusion?

The five review criteria are the same for TRAN1-4, but readiness, activities and outcomes vary by program.

GWG Recommendations

Score	Number of Apps	Total Applicant Request	Funds Available
Recommended for funding Score of 85-100	17	\$78,156,321	\$60,000,000
Not recommended for funding Score of 1-84	15		

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.

No applications qualified for a Minority Report for this cycle

CIRM Team Recommendations

Score	Number of Apps	Total Applicant Request	Funds Available
Recommended for funding Score of 85-100	13	\$57,495,823	\$60,000,000
Not recommended for funding Score of 1-84	19		

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.