

Real Life™

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Revision to CLIN2 Concept
July 28, 2022

CIRM
CALIFORNIA'S STEM CELL AGENCY

Therapeutic candidates eligible for clinical trial awards

Currently, the CLIN2 program allows clinical trial studies with a candidate that is either a:

- Stem cell therapy
 - Genetic therapy
- } Phase 1, 2, or 3 trials
- Small molecule or biologic involving stem cells
- } Phase 1 trials only

Therapeutic candidates eligible for clinical trial awards

We propose unifying eligibility to allow all 3 categories to qualify for a phase 1, 2, or 3 clinical trial

- Stem cell therapy
 - Genetic therapy
 - Small molecule or biologic involving stem cells
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- Phase 1, 2, or 3 trials

Allows for consistent eligibility requirement across all clinical applications and provides the possibility of ongoing CIRM support for small molecule/biologic projects that are ready to advance to late-stage clinical trials.

Existing eligibility language would be extended to phase 2 and phase 3 clinical trials:

“A small molecule or biologic that acts on or is dependent on endogenous human stem cells for its therapeutic effect, that is dependent on targeting human cancer stem cells for its therapeutic effect, that modifies a stem cell therapy, OR where a human stem cell is necessary to manufacture the therapy (e.g., extracellular vesicles).”

Additional minor revisions:

A few additional edits have been included in the concept document that represent a clarification in the text.

- “Gene therapy” to “Genetic therapy”

There are a few instances where this update was missed in the last round of changes to align with adopted definition of “genetic therapy”

- Clarification that feasibility trials for medical devices are included within the requirements for award amount limits and co-funding amounts.

CIRM requests approval of the proposed amendments to the CLIN2 concept plan.