

CLIN2 Guiding Principles & Review Process

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Short Video

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Agenda

- CLIN2 Overview and Guiding Principles
- Volume Control
- Application Selection Process
- Where to Find More Information

CLIN2 Overview and Guiding Principles

CLIN2 | Award Structure

	CLIN2		
	First-in-Human	Phase 2 or subsequent*	Phase 3 or pivotal
Recurrence	4x per year		
Max Duration	4 years		
Applicant	California or non-California organizations		
Co-funding**	30% (for-profit**) None (non-profit)	50% (for-profit**) None (non-profit)	50%
Max Award (Total Cost)	\$8M (for-profit) \$12M (non-profit)	\$15M	\$15M

* “Subsequent” trials are any phase 1 trials following a First-In-Human trial in the proposed disease indication and using a given route of administration.

**Co-funding requirement also applies to for-profit partners of non-profit applicants.

Guiding Principles: CLIN2

Guiding principles help CIRM shape its portfolio

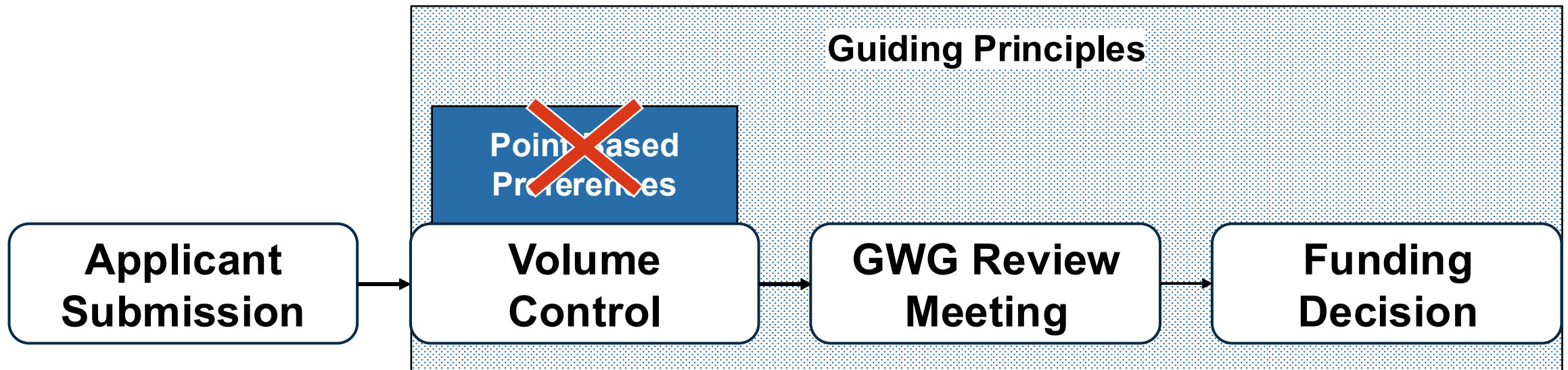
The CLIN2 portfolio will:

- Offer transformative impact for patients, meaning therapies that provide significant benefits over existing therapies and those in clinical trials
- Address known barriers to access of stem cell-based and genetic therapies
- Broadly address both prevalent and rare diseases affecting Californians

Volume Control

Purpose of Volume Control Step

- The number of applications received for many funding opportunities often exceed the capacity of the GWG to appropriately review in a single cycle.
- Previously, preferences were used for volume control in the CLIN2 program.



Application Selection Process

CLIN2 GWG Application Selection Criteria

- The therapy's potential to provide a meaningful and significant improvement in clinical outcomes compared to therapies currently available or in development.
- Impact of addressing the unmet medical need on patients, caregivers and the healthcare system.
- Feasibility and practicality of the therapy's uptake by patients, caregivers, and the healthcare system

Changes to Volume Control Process

	Initial Volume Control/Selection	Resolution of Ties
Previous Process - Qualification	<p>> 7 applications received:</p> <p>7 applications with the highest scores, based on preference points, proceeded to GWG review meeting</p>	<p>Ties for 7th slot, if present, were broken by GWG assessment of Value Proposition</p>
Revised Process - GWG Application Selection	<p>> 10 applications received:</p> <p>Applications receive a composite score based upon evaluation of scientific value by GWG reviewers; approximately 10 of the top scoring applications will proceed to GWG discussion and recommendations</p>	<p>Ties for final slot, if present, are broken by random selection</p>

Where to Find More Information

Resources

- [CLIN2 Program Announcement](#)
- [CLIN2 Website](#)
- [Quick Guide](#)

Questions? Contact clinical@circm.ca.gov.

Thank You!

Please visit us at:
www.cirm.ca.gov

