

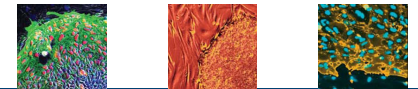
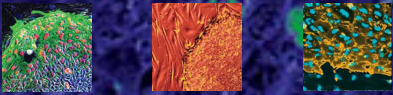


CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Reconsideration of Alpha Clinics Concept Plan: CIMC

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July 24, 2014



Mission of the Current Proposal



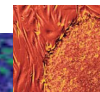
Mission: *To accelerate therapeutic development and delivery of stem cell therapies*



Stated Goals of the Current Proposal

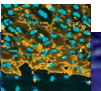
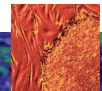
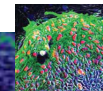
Network has the following overarching goals:

- **Clinical Trials**: Develop resources and leverage existing infrastructure to address the unique challenges and needs of testing and delivering conceptually novel investigational stem cell products
- **Delivery of Therapies**: Facilitate the delivery of approved stem cell-based therapies to the clinics
- **Data and Information**: Compile information about stem cell clinical trial experience and outcomes, and support data analysis to inform research, clinical, regulatory and reimbursement decisions
- **Educating Patients and the Public**: Create tools and assemble staff to provide patients and public education, outreach and training regarding legitimate stem cell therapies and trials. Educate and inform the public about the issues of “stem cell tourism” whereby unproven and unregulated interventions and products are sold to patients
- **Healthcare Economics**: Develop an evidence base to support the development of sustainable business models including reimbursement strategies



A Two Part Concept Plan

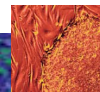
- **The Alpha Clinics sites**
 - Funding for up to five sites for up to five years
 - Does not build any physical infrastructure nor directly fund proposed clinical trials
 - Mainly covers personnel costs
 - Approximately \$11 M each for a five year total of \$55M
- **The CIMC**
 - Funding for one site for five years
 - A five year total of \$15 M
- **Total - \$70 million over five years**



Critical Assessment

- The concept plan contains many laudable activities
- However, the plan lacks focus and attempts to address too many issues
- There is a very real possibility of duplication of costs
- The \$70 million price tag is not clearly justified in terms of the benefits it will deliver to the people of California

Programs that try to fix everything, tend to fix nothing



Proposed Approach

Narrow the focus to those activities that accelerate patient participation

- **Continue with the “clinics” portion of the concept plan**
 - Conduct the review of applications in September
 - Recommend a limited number of centers for initial funding (*will be discussed during programmatic review at a later meeting*)
 - Objectively evaluate the success of the program and modify (accelerate, stop, or fix based upon results)
- **Revise the CIMC portion of the concept plan**
 - Narrow the focus to clinical operations (other topics can be addressed in separate concept plans)
 - Reissue an RFA for the focused CIMC

