Alpha Stem Cell Clinics Network: Concept Proposal

July 25, 2013
Alpha Clinics: Addressing unmet needs in clinical infrastructure for stem cell therapies

- Development of stem cell therapeutics is on the rise
Alpha Clinics: Addressing unmet needs in clinical infrastructure for stem cell therapies

- Development of stem cell therapeutics is on the rise
- Testing and delivery of stem-cell based products present unique challenges
Mission: Create resources, know-how and efficiencies to accelerate clinical testing and delivery of stem cell-based products

Alpha Clinics Network

Preclinical Dev. → Phase 1 Clinical Research → Phase 2 Clinical Research → Phase 3 Clinical Research → Delivery of approved therapies

Focus (2011-2016)
- Drive clinical trials for patients to generate preliminary evidence of therapeutic benefit

Deliver (2016+)
- Advance therapies to patients
- Facilitate commercialization of therapies
- Enable business model for stem cell-based therapies
Alpha Stem Cell Clinics Network Attributes

- **CLINICAL TRIALS**: Develop resources designed for effective and efficient design and execution of clinical trials for investigative stem cell products.

- **DELIVERY OF THERAPIES**: Become a center of excellence for delivery of stem cell-based therapies that have been proven safe and effective.

- **DATA AND INFORMATION**: Compilation of information about clinical trial experience and outcomes, and data to inform research, clinical, regulatory and reimbursement decisions.

- **INFORM THE PUBLIC**: Education, outreach and training about clinical trials and available therapies, and potential dangers of unproven procedures.

- **HEALTHCARE ECONOMICS**: To serve as a “proving ground” to develop business models, and to develop evidence base and strategy for reimbursement.
Focus of Alpha Stem Cell Clinics Network

- Stem-cell derived products that are novel as opposed to modifications of therapies in current medical practice

- Procedures that require transplantation or infusion of cells, as opposed to small molecules or biologics
Alpha Clinics: five sites distributed throughout California

- Conduct clinical trials
- Patient Education & Counseling
- Delivery of approved therapies
Coordinating and Information Management Center (CIMC)

- Outreach, education and training (OET)
- Consulting services
  - Clinical
  - Regulatory
  - Biostatistics
- Patient Registry and Database
- Healthcare economics and business development
Long-term vision: A robust network to test and deliver stem cell-based therapies
Alpha Clinics Would Serve Patients Seeking Stem Cell Treatments

Alpha Clinics
- Counselors
- Clinical Trial Team

CIMC
- Quality Information
- Rigorous Standards
- Efficiencies

Clinical Resources & Infrastructure

www.pligofsj.com
manila.olx.com.ph
Network Resources & Efficiencies for Stem Cell Clinical Research

**Alpha Clinics**
- Trial Enrollment
- Experienced Clinical Trial Team

**CIMC**
- Database and Registry
- Clinical, Regulatory Support & Know-how
- Standardized Forms & Approaches

**Clinical Resources & Infrastructure**
- IRB
- Clinical Trial Agreements
- Medical & Ancillary Services

**Clinicians**
- Researchers
- Sponsors
## Eligibility and Scope

<table>
<thead>
<tr>
<th>Alpha Clinics</th>
<th>CIMC</th>
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<tbody>
<tr>
<td>• California Institution with a Medical Center- one alpha clinic award per institution</td>
<td>• Existing California for-profit or non-profit entity</td>
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<tr>
<td>• PI &amp; Team with strong track record in Medical Care and Clinical Research</td>
<td>• Strong track record in clinical trial management &amp; support</td>
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<td>• Institutional commitment to leverage existing infrastructure and resources</td>
<td>• In-house clinical, scientific, regulatory, database, business expertise and PI with strong management &amp; administrative skills (experience with cell-based products)</td>
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<tr>
<td>• Strong track record for clinical trials &amp; large patient and referral base</td>
<td>• Commitment to set up public education and outreach activities</td>
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<td>• Can initiate at least one stem cell trial within 12 months of the award date</td>
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<td>• Sustainability and Pipeline of stem cell clinical activities</td>
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Proposed CIRM Funding to form the Alpha Clinics Network

<table>
<thead>
<tr>
<th>RFAs</th>
<th>Length</th>
<th># Awards</th>
<th>Total cost up to</th>
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<tbody>
<tr>
<td>Alpha Clinics</td>
<td>5 year</td>
<td>Up to 5</td>
<td>$55 million</td>
</tr>
<tr>
<td>CIMC</td>
<td>5 year</td>
<td>1</td>
<td>$15 million</td>
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- Two RFAs
- Request approval for a total of $70 million
# Provisional Time Table for Alpha Clinics Network RFAs

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
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<tbody>
<tr>
<td>Release of RFAs</td>
<td>October 2013</td>
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<tr>
<td>Letters of Intent due</td>
<td>December 2013</td>
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<tr>
<td>Applications due</td>
<td>March 2014</td>
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<tr>
<td>GWG Review of Applications</td>
<td>May 2014</td>
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<tr>
<td>Funding Recommendations to ICOC</td>
<td>July 2014</td>
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