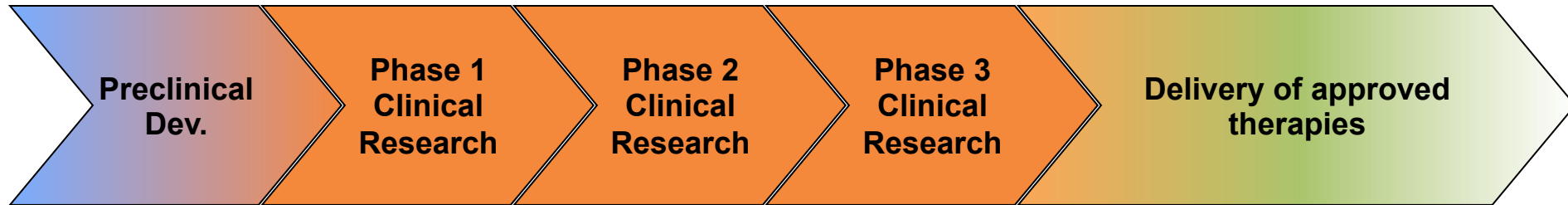


# Alpha Stem Cell Clinics Network: Concept Proposal

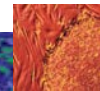
**July 25, 2013**

# Alpha Clinics: Addressing unmet needs in clinical infrastructure for stem cell therapies

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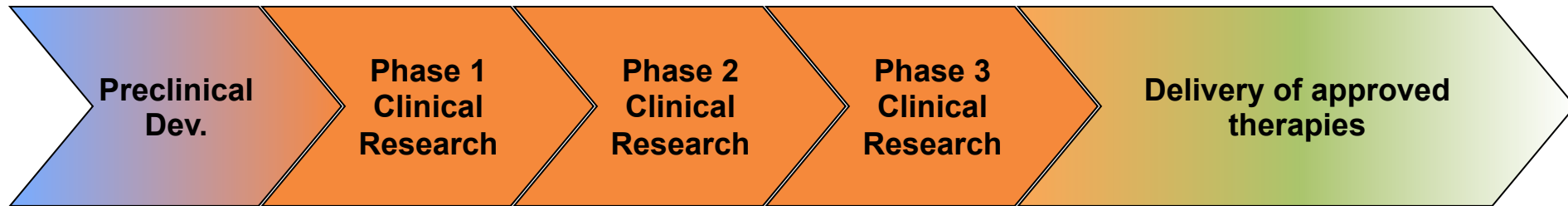


- **Development of stem cell therapeutics is on the rise**

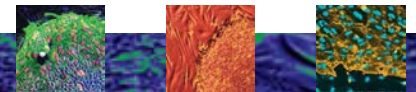


# Alpha Clinics: Addressing unmet needs in clinical infrastructure for stem cell therapies

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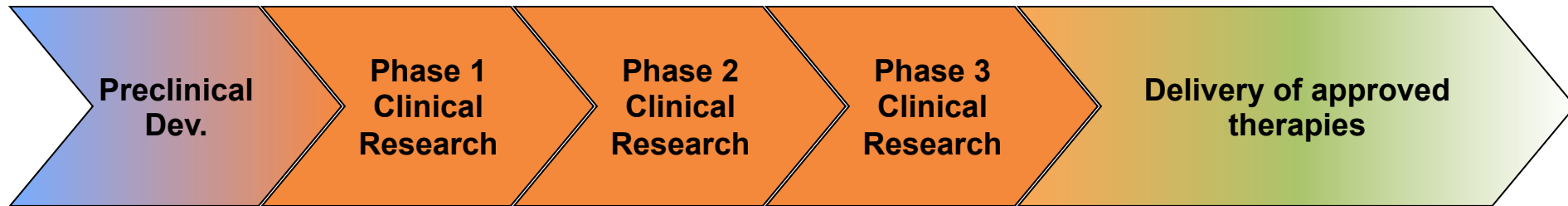


- **Development of stem cell therapeutics is on the rise**
- **Testing and delivery of stem-cell based products present unique challenges**



# Mission: Create resources, know-how and efficiencies to accelerate clinical testing and delivery of stem cell-based products

## Alpha Clinics Network

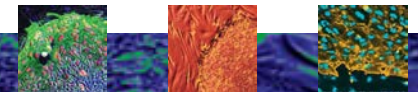


### Focus (2011-2016)

- Drive clinical trials for patients to generate preliminary evidence of therapeutic benefit

### Deliver (2016+)

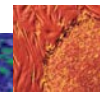
- Advance therapies to patients
- Facilitate commercialization of therapies
- Enable business model for stem cell-based therapies



# Alpha Stem Cell Clinics Network Attributes

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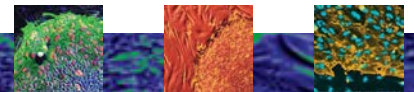
- **CLINICAL TRIALS:** Develop resources designed for effective and efficient design and execution of clinical trials for investigative stem cell products
- **DELIVERY OF THERAPIES:** Become a center of excellence for delivery of stem cell-based therapies that have been proven safe and effective
- **DATA 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

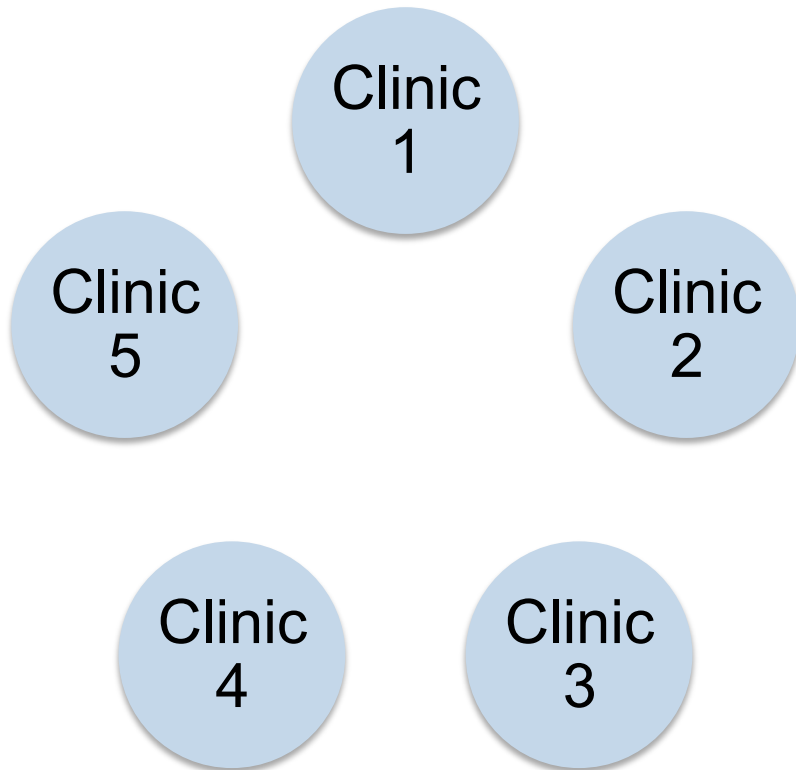
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- Stem-cell derived products that are novel as opposed to modifications of therapies in current medical practice
- Procedures that require transplantation or infusion of cells, as opposed to small molecules or biologics



# Alpha Clinics: five sites distributed throughout California

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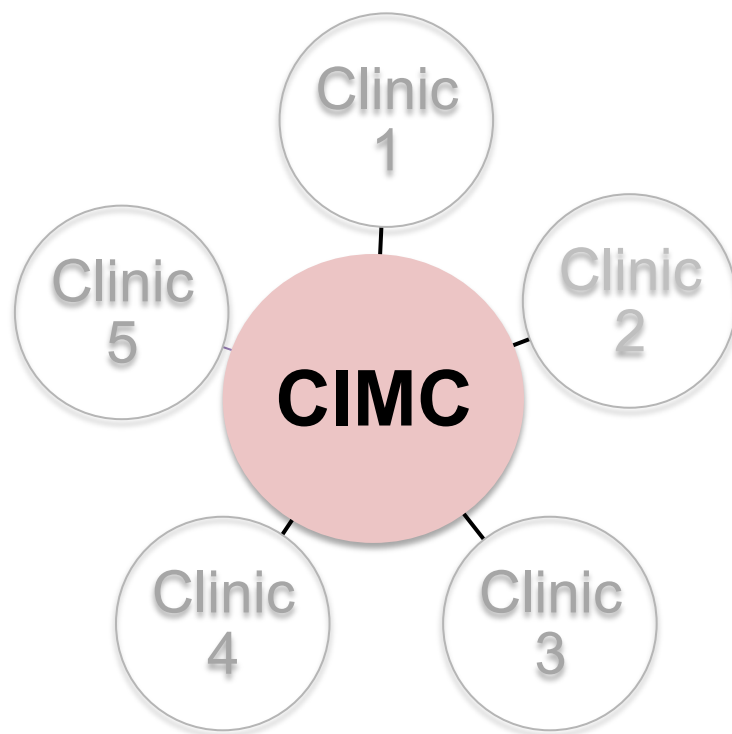


- **Conduct clinical trials**
- **Patient Education & Counseling**
- **Delivery of approved therapies**



# Coordinating and Information Management Center (CIMC)

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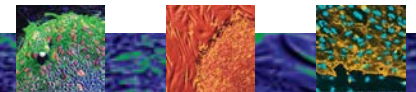
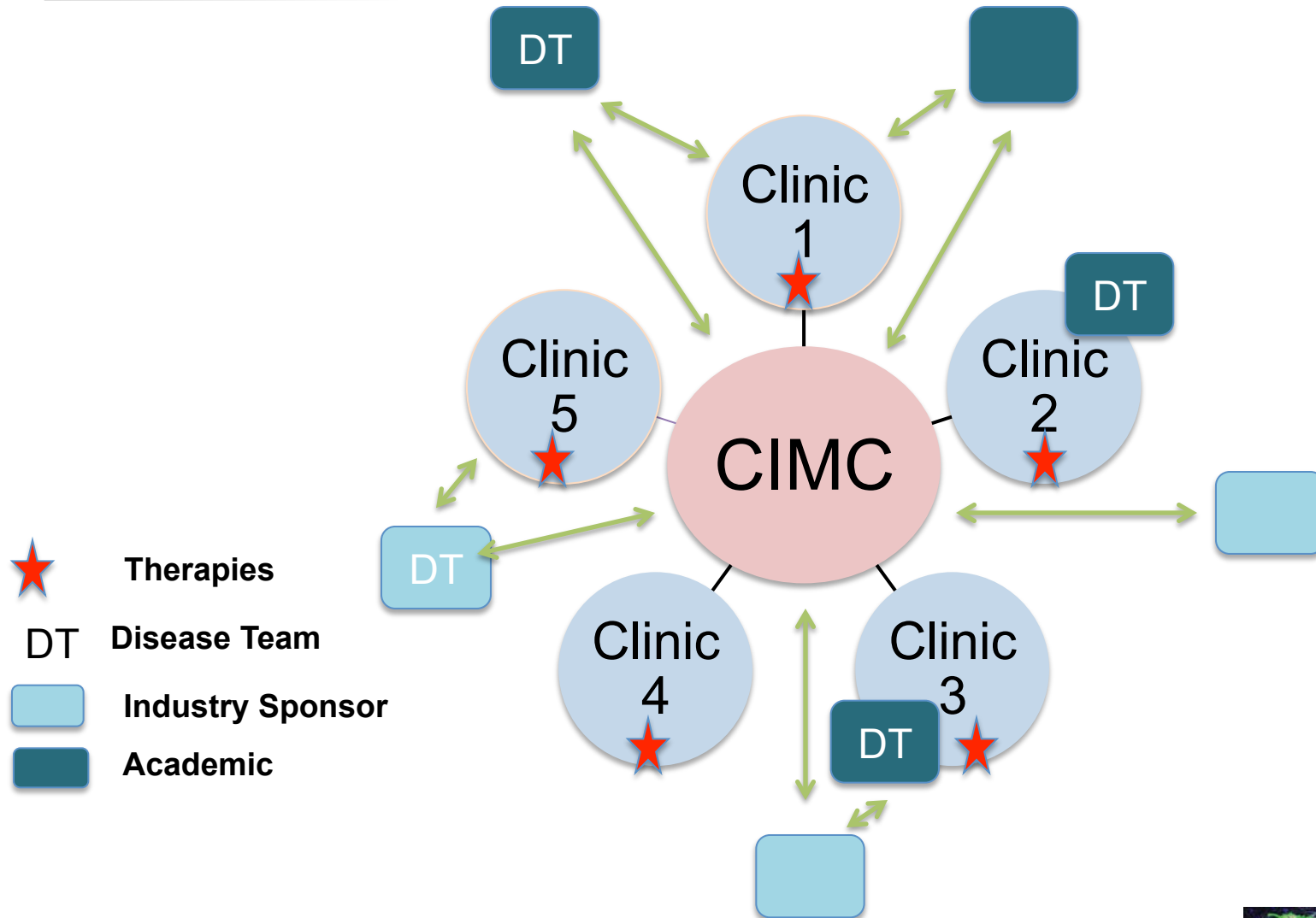


- **Outreach, education and training (OET)**
- **Consulting services**
  - Clinical**
  - Regulatory**
  - Biostatistics**
- **Patient Registry and Database**
- **Healthcare economics and business development**

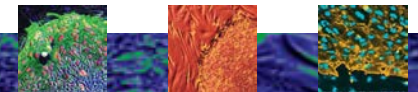
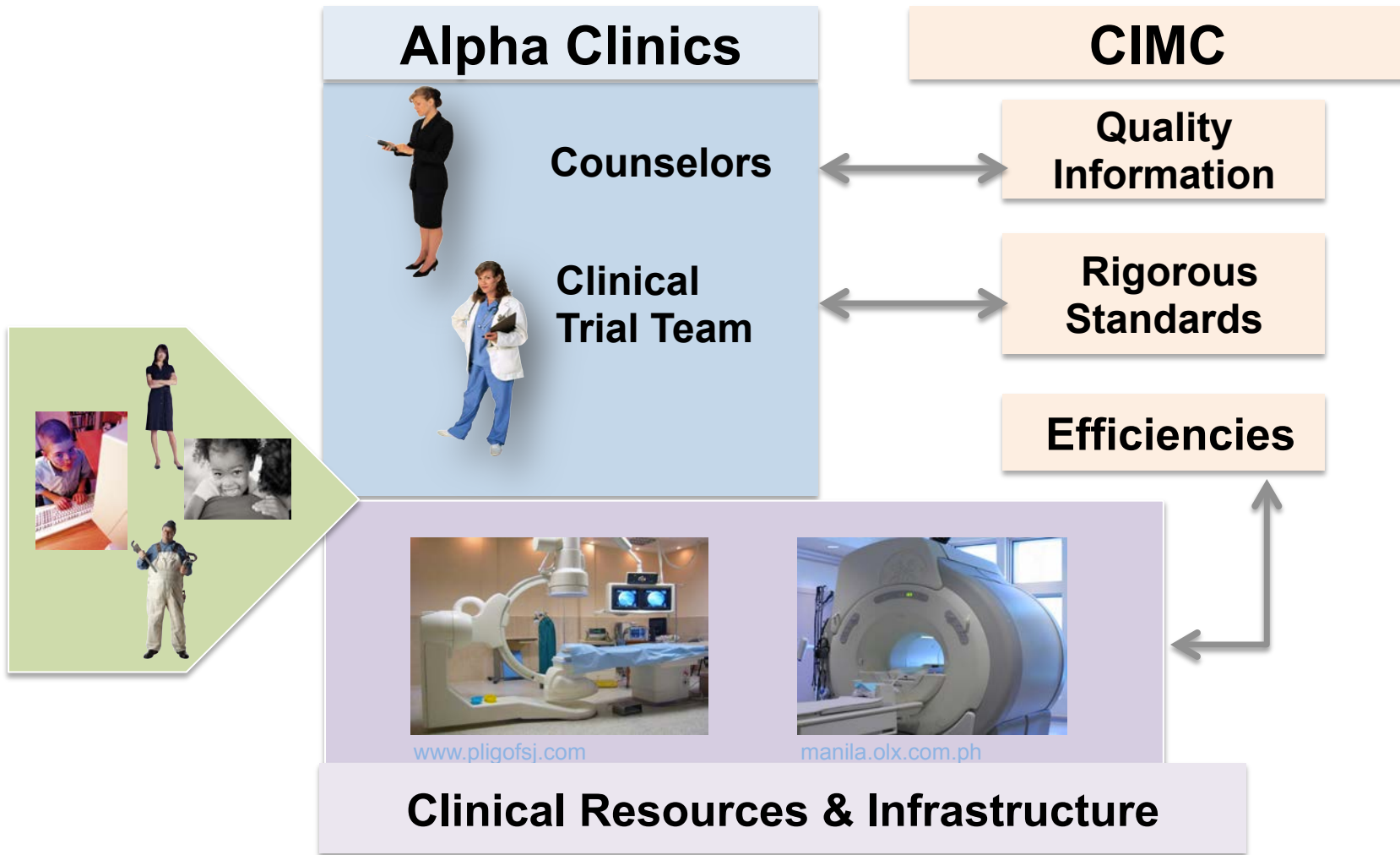




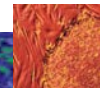
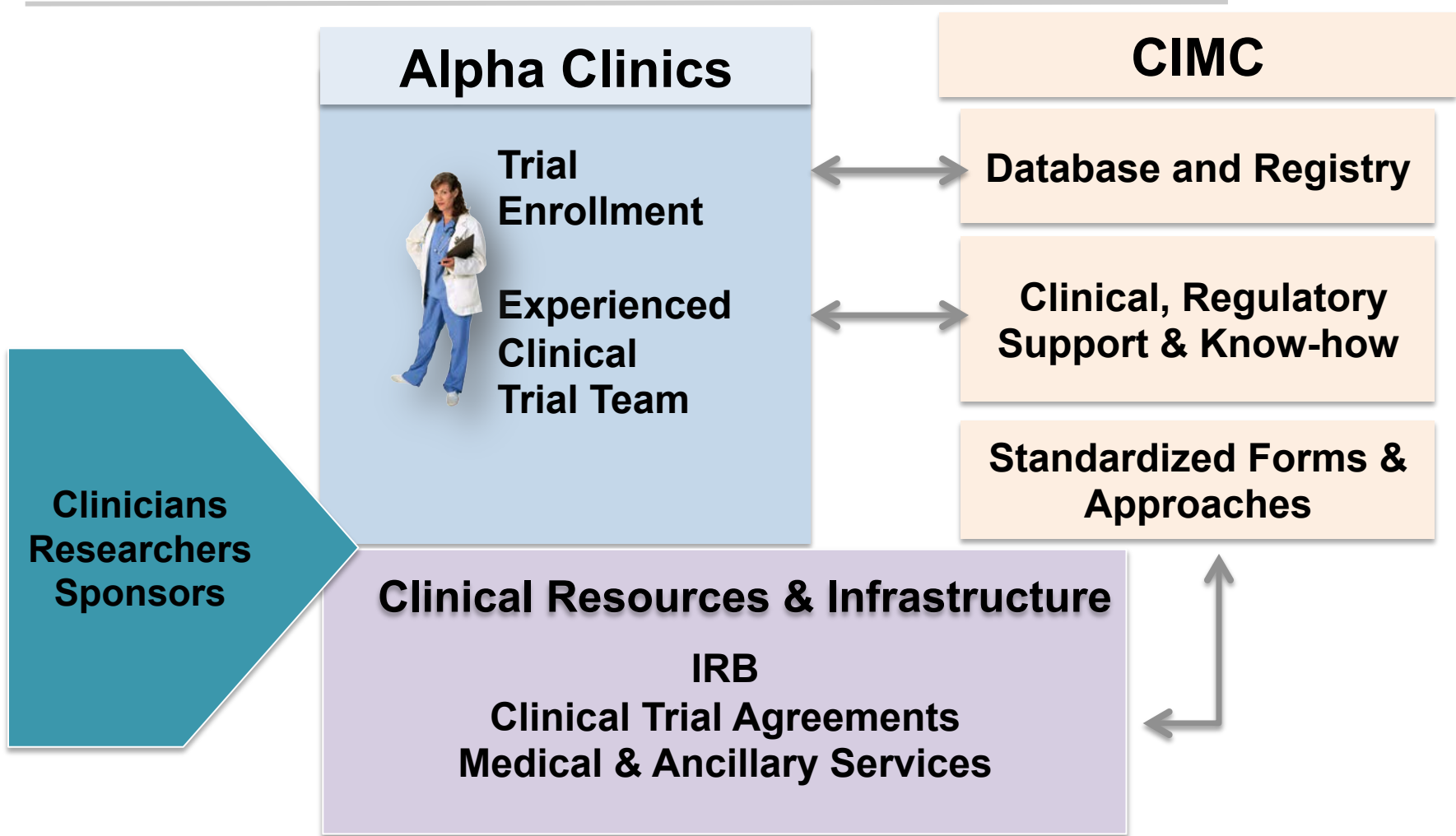
# Long-term vision: A robust network to test and deliver stem cell-based therapies



# Alpha Clinics Would Serve Patients Seeking Stem Cell Treatments



# Network Resources & Efficiencies for Stem Cell Clinical Research



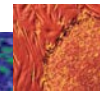
# Eligibility and Scope

## Alpha Clinics

- California Institution with a Medical Center- one alpha clinic award per institution
- PI & Team with strong track record in Medical Care and Clinical Research
- Institutional commitment to leverage existing infrastructure and resources
- Strong track record for clinical trials & large patient and referral base
- Can initiate at least one stem cell trial within 12 months of the award date
- Sustainability and Pipeline of stem cell clinical activities

## CIMC

- Existing California for-profit or non-profit entity
- Strong track record in clinical trial management & support
- In-house clinical, scientific, regulatory, database, business expertise and PI with strong management & administrative skills (*experience with cell-based products*)
- Commitment to set up public education and outreach activities



# Proposed CIRM Funding to form the Alpha Clinics Network

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<b>RFAs</b>	<b>Length</b>	<b># Awards</b>	<b>Total cost up to</b>
Alpha Clinics	5 year	Up to 5	\$55 million
CIMC	5 year	1	\$15 million

- Two RFAs
- Request approval for a total of \$70 million



# Provisional Time Table for Alpha Clinics Network RFAs

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<b>Release of RFAs</b>	October 2013
<b>Letters of Intent due</b>	December 2013
<b>Applications due</b>	March 2014
<b>GWG Review of Applications</b>	May 2014
<b>Funding Recommendations to ICOC</b>	July 2014

