



Shyam Patel, Ph.D. & Sohel Talib, Ph.D.

Manufacturing Network Concept Plan Presentation

ICOC Science Subcommittee Meeting

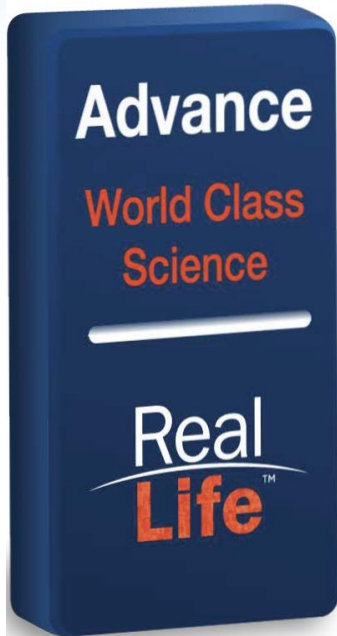
July 28, 2022



OUR MISSION

Accelerating world class science
to deliver transformative
regenerative medicine treatments
in an equitable manner to a
diverse California and world





- Develop Competency Hubs
- Build Knowledge Networks



- Advance therapies to marketing approval
- **Create a manufacturing partnership network**
- Expand Alpha Clinics Network
- Create Community Care Centers of Excellence



- Build a diverse and highly skilled workforce
- Deliver a roadmap for access and affordability

- **Academic Institutions are the center of technology innovation and initial process development and GMP manufacturing** but don't have sufficient capacity, resources or processes for late-stage manufacturing.
- **Industry Contract Development & Manufacturing Organizations (CDMOs) or in-house operations are best positioned to industrialize manufacturing processes** for later-stage clinical trials and commercialization but don't always have expertise in emerging technology platforms arising from academia.
- The complexities of the products and processes create various technical bottlenecks.
- There is an ever-growing demand for a trained manufacturing and quality workforce.

Academic GMP Manufacturing Facilities (utilized by majority of CIRM-funded projects)

- Cedars Sinai
- City of Hope
- Stanford
- UC Davis
- UC Irvine
- UC Los Angeles
- UC San Diego
- UC San Francisco
- USC/CHLA

Industry GMP Manufacturing Facilities (capable of accepting external projects)

CDMOs (fee for service/partnerships)

- Allele Bio
- Cellipont
- Fujifilm Diosynth
- Millipore Sigma
- Miltenyi
- Minaris
- Resilience
- Thermo Fisher
- Synthego

Biopharma (partnerships)

- Bayer
- Novo Nordisk

CIRM-Funded Academic GMP Facility Network



Industry Partners

- Manufacturing services
- Resources
- Investment and Partnerships

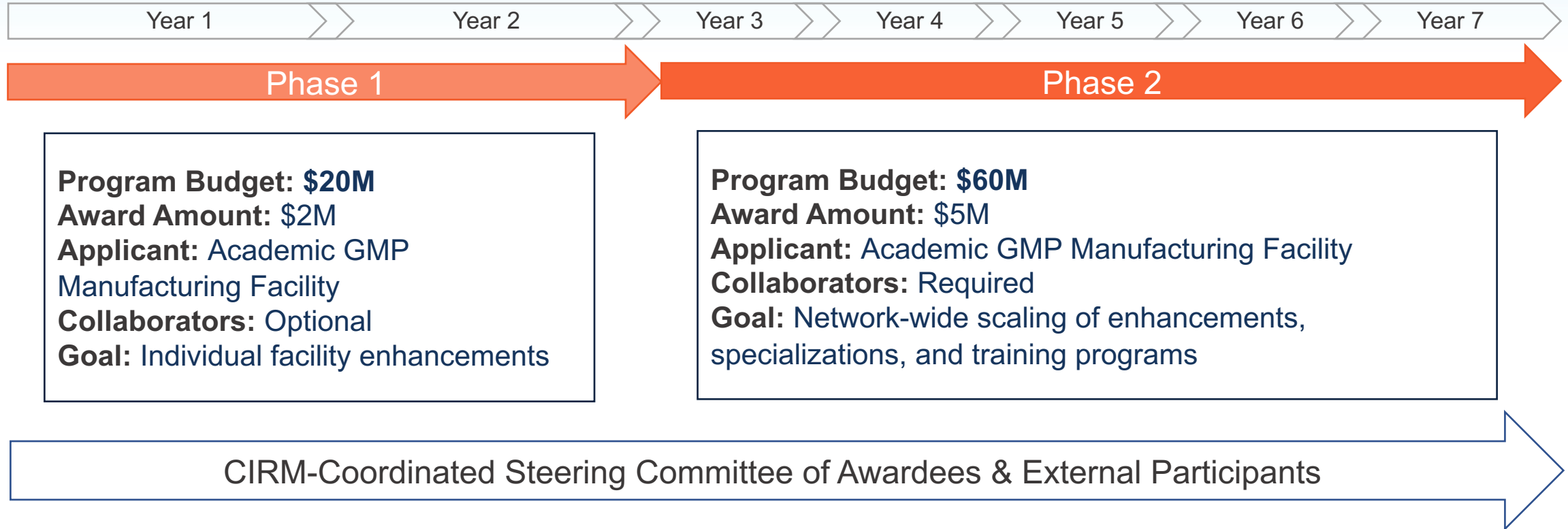


- **Accelerate**
and de-risk path to commercialization
- **Advance**
standards and quality by design
- **Build**
manufacturing leadership and workforce

Potential Functions of the Cell & Gene Therapy Manufacturing Network

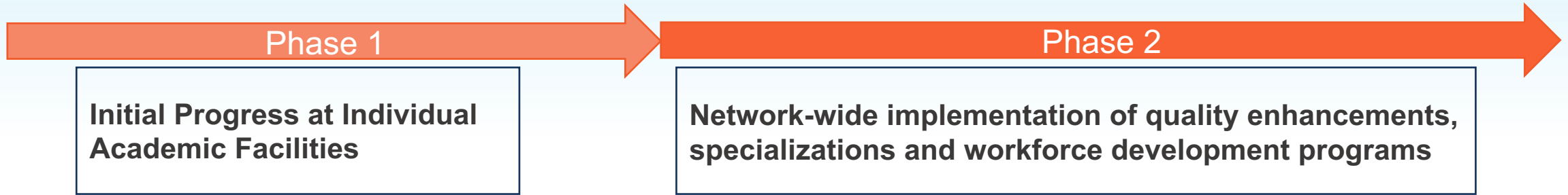
- World-class expertise across range of manufacturing and analytical technology platforms
- Support manufacturing of therapies for rare and ultra-rare diseases
- Accelerate and de-risk late-stage and commercial manufacturing of therapies
- Establish standards for quality or accreditation of manufacturing facilities
- Build inclusive workforce entry and advancement opportunities in technical and leadership career pathways in partnership with EDUC programs and industry stakeholders

Bi-Phasic Funding Opportunity



CIRM-Funded Academic GMP Facility Network ↔ **Industry Partners**





De-Risk & Accelerate Manufacturing

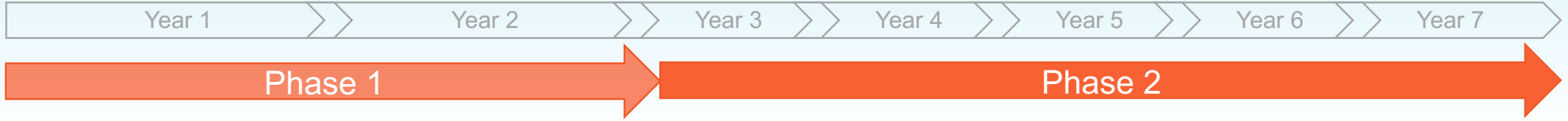
- Implement quality-driven operational enhancements that de-risk process development, GMP manufacturing and technology transfer from pre-IND through to commercialization.
- Actively mitigate capacity & expertise gaps by coordinating project execution across the network.

Specialized Offerings

- Build network-wide specialization in areas such as technology platforms, analytical methods, quality-by-design, automation, N-of-1 manufacturing, etc.

Workforce Development

- Develop and implement training programs for technical and leadership positions in partnership with EDUC and industry stakeholders.



Individual Awardees:

- Quality system improvements
- Implementation of Quality-by-Design principles
- Hiring and/or training of staff

Potential Outcome Metrics:

- Impact of quality-driven improvements on project execution compared to historical performance.

Awardees & Collaborators:

- Scale quality improvements across the network
- Operationalize partnerships to effectively transition projects for late-stage/commercial manufacturing

Potential Outcome Metrics:

- Success rate of partnership-driven progression of projects to late-stage and commercial manufacturing.
- Application of network-wide quality standards, protocols and best practices.

Phase 1

- Impact of quality-driven improvements on project execution compared to historical performance.
- Demonstrate competency in specialization areas by executing pilot project(s).
- Enroll first trainee cohorts for technical and leadership training programs.

Phase 2

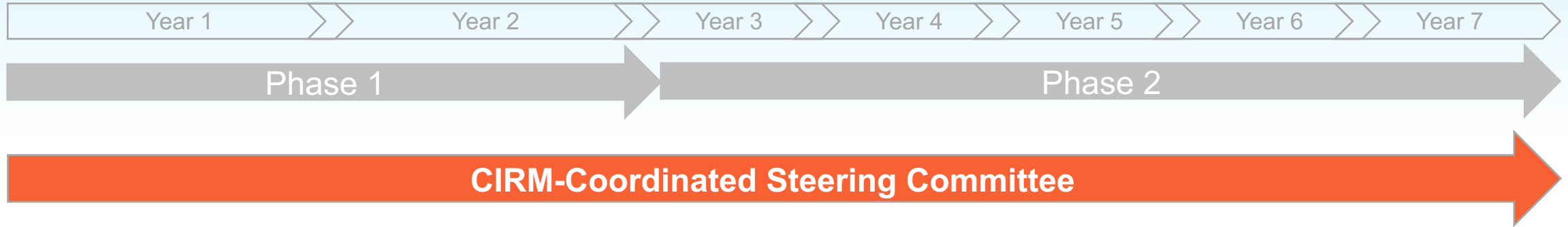
- Success rate of partnership-driven progression of projects to late-stage and commercial manufacturing.
- Utilization rate of specializations by collaborating facilities.
- Application of network-wide quality standards, protocols and best practices.
- Sustained enrollment in training programs and success rate of trainee job placement.

Must Include Plans to Address DEI

- Participation in workforce development programs by underserved populations
- Project team represents diverse and inclusive perspectives and experiences

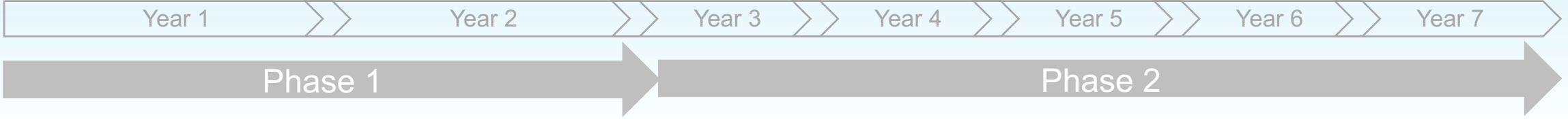
Must Include Knowledge Sharing Plans

- Describe plan to capture and disseminate relevant know how, operational data, processes, expertise and guidance within network
- Describe any knowledge sharing plans critical to achieving award objectives
- Describe data management processes that will support CIRM TRAN/CLIN awardees to execute on their respective data management & sharing plans



CIRM will coordinate Steering Committee of awardees, California industry partners & national stakeholders to facilitate:

- Identification and adoption of standards, protocols and best practices across the network and potential criteria for facility accreditation
- Mitigation of capacity and expertise gaps across participating sites
- Collaborative planning for Phase 2 proposals
- Development of systems and processes for sharing information and resources between network participants
- Collaborative development and implementation of workforce training programs



Individual Awardees:

- Quality system improvements
- Implementation of Quality-by-Design principles
- Hiring and/or training of staff

Awardees & Collaborators:

- Scale quality improvements across the network
- Operationalize partnerships to effectively transition projects for late-stage/commercial manufacturing



Steering Committee:

- Identifying quality standards for academic GMP facilities
- Defining knowledge sharing processes

Steering Committee:

- Apply quality standards across network
- Facilitate knowledge sharing within network
- Triage projects by expertise/capacity across network

Program Budget

- **\$80M Total.** Phase 1 - \$20M; Phase 2 - \$60M

Awards

- **Award Caps:** Phase 1 - \$2M; Phase 2 - \$5M
- **Allowable costs:** Direct Project Costs & Direct Facilities Costs.
- **Co-Funding:** 20% both phases

Who can apply?

- California non-profit GMP manufacturing facilities with track record of cell and gene therapy project support.

Real LifeTM

CIRM
CALIFORNIA'S STEM CELL AGENCY