

PACT

Production Assistance for Cellular Therapies



14th Annual ASGCT Meeting
Translational Science Training Course
-Resources-

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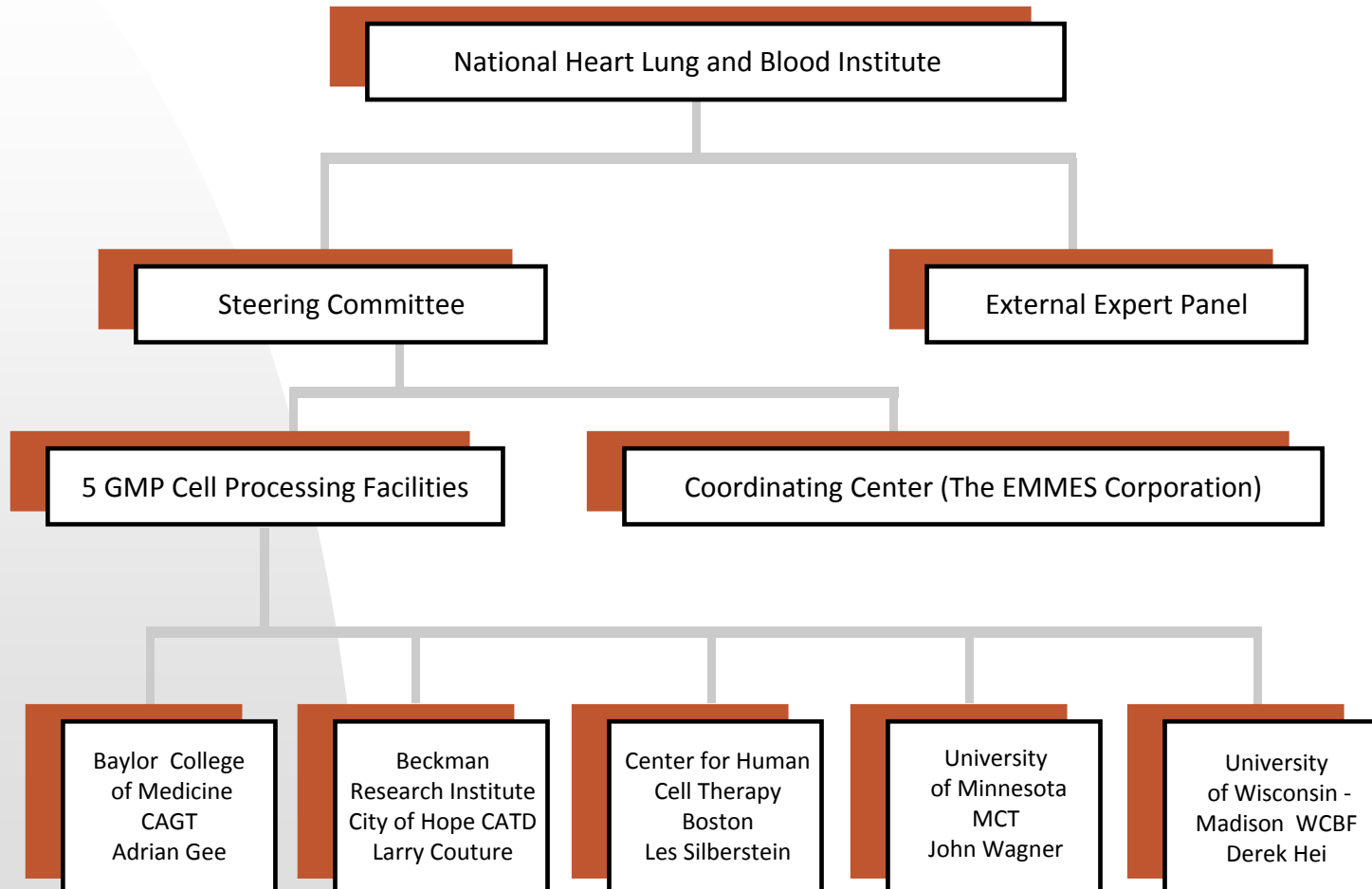
PACT Program

- NHLBI funded initiative
- Began in September 2003
- Renewed in January 2010
- # of facilities, scope, and interest expanded

Objective

Provide assistance with cellular therapy translational research and the manufacture of cellular therapy products

PACT Organizational Structure



Application Requests

■ Products and Services

- Products that aid in the repair and regeneration of damaged/diseased tissues, organs, and biologic systems
- Preclinical/translational studies including animal model work
- Products of programmatic interest to the Institute and associated with a funded clinical study
- Proposals possessing procedural advancements to further foster and standardize cell therapies

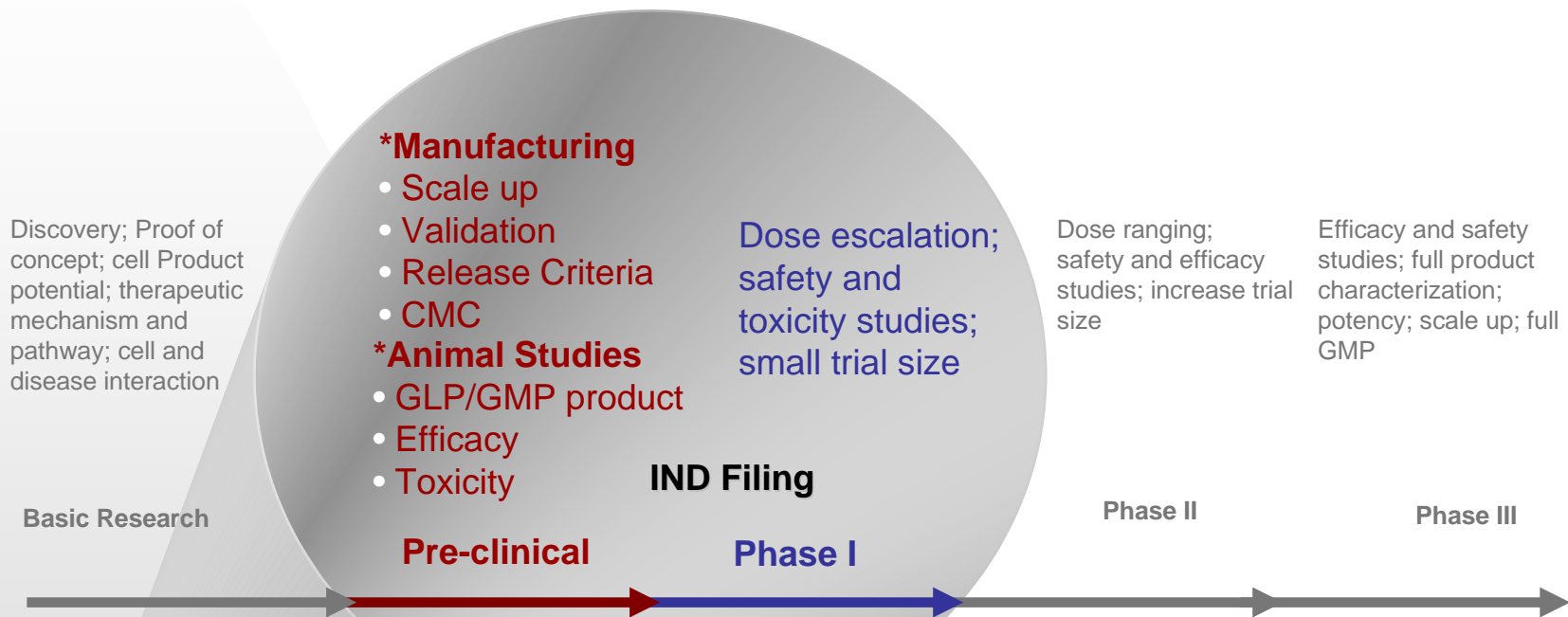
NHLBI Scope

- Cardiac repair and disease
- Lung repair and disease
- Complications of malignancy treatment
 - GVHD
 - Post transplant viral infections
- Hematologic disease outside of primary treatment for malignancy

Expanded Interest

- Support for translational work
 - All translational work will be evaluated
- Specific support for GMP translational work not funded through standard NHLBI grant mechanisms

PACT's Role in Supporting Pre-Clinical Work and Phase I Clinical Trials



PACT Manufacturing Models

- Centralized Manufacturing
 - Provide single or multiple sites without manufacturing capability with clinical product
- Distributive Manufacturing
 - Manufacturing occurring at multiple sites

PACT Program Status

- 40 ongoing projects
 - 23 - Clinical
 - 12 - Delivering clinical product (cardiac; GVHD; post transplant viral infections; hematological malignancies; X-linked severe combined immunodeficiency [SCID-X1])
 - **17 - Translational** (pre-clinical animal studies for cardiac & lung indications; Wiskott Aldridge Syndrome Protein deficiency; stem cells for corneal transplantation)

PACT Application Process

- Web based Preliminary Application
- Concept Review by Steering Committee
- Full Application invited
- Web based Full Application
- Independent Reviews
- Facility and Technical Liaison Assignment
- Budget, Contract & Timeline

Contact Information

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