Cell Product Manufacture

- **Cell products for IND enabling studies and early phase clinical studies**
- **cGMP / Scale-up cell product manufacturing**
- **Development of Product SOPs / Batch Production Records / CMC**
- **Manufacturing Process / Equipment Validation**
- **Product Release Specifications, Testing, and Certificate of Analysis**

Regulatory Service Support

- **Project Gap Analysis**
- **Pre-clinical study design**
- **Guidance for INTERACT / pre-IND discussions with FDA**
- **INTERACT / pre-IND meeting package and planning**
- **IND consultation and review**

Emmes

PACT Coordinating Center
The Emmes Company, LLC
401 N. Washington Street #700
Rockville, MD 20850

PACT Mission

Provide regulatory services, assistance with cellular therapy translational research and the manufacture of cellular therapy products for pre-clinical and early phase clinical studies.

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PACT Cell Processing Facilities

Center for Cell and Gene Therapy (CAGT)
Baylor College of Medicine
HHSN268201600015I

Center for Biomedicine and Genetics
City of Hope
HHSN268201600011I

Interdisciplinary Stem Cell Institute
Cellular Manufacturing Program (ISCI-CMP)
University of Miami
Miller School of Medicine
HHSN268201600012I

University of Minnesota
Molecular and Cellular Therapeutics (MCT)
HHSN268201600014I

Moffitt Cancer Center
HHSN268201600013I

- Coordinating Center -
The Emmes Company, LLC
HHSN268201600020C

City of Hope

MOLECULAR & CELLULAR THERAPEUTICS
UNIVERSITY OF MINNESOTA
Driven to Discover℠

CAGT CENTER FOR CELL AND GENE THERAPY

MOFFITT CANCER CENTER

Baylor College of Medicine · Texas Children's Hospital · Houston Methodist

ISCI interdisciplinary stem cell institute
UNIVERSITY OF MIAMI MILLER SCHOOL OF MEDICINE

NIH National Heart, Lung, and Blood Institute

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Regulatory, Clinical and Translational Cell Manufacturing Services

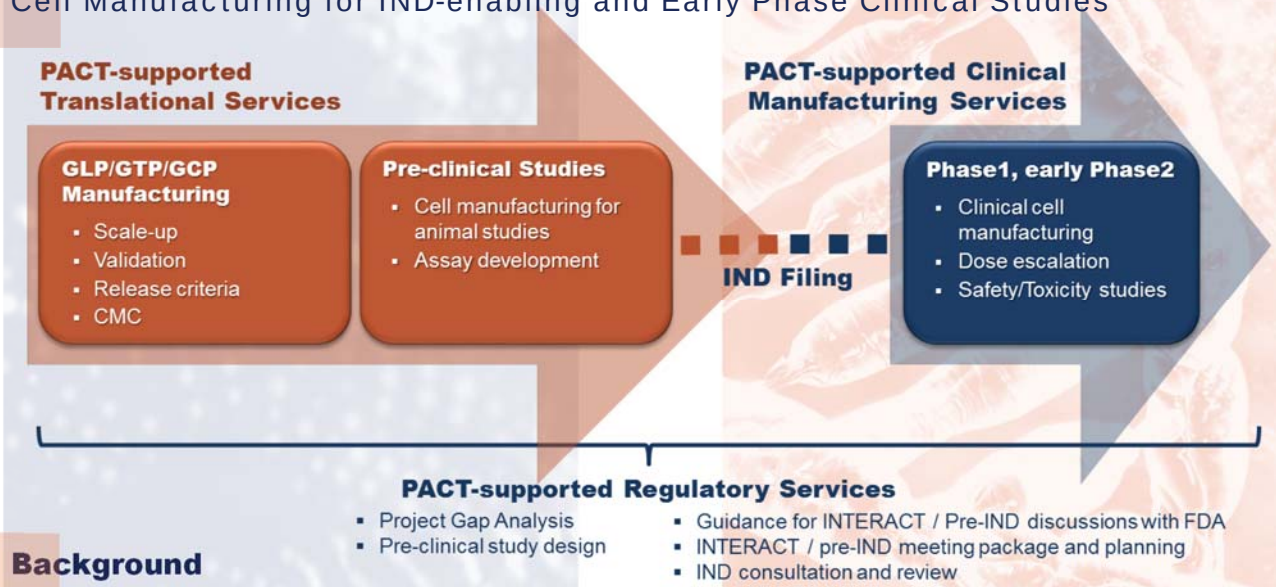
Partners in the Development of Cell Therapies

PACT

Production Assistance for Cellular Therapies
National Heart Lung and Blood Program

www.pactgroup.net

Cell Manufacturing for IND-enabling and Early Phase Clinical Studies



Background

The National Heart, Lung, and Blood Institute (NHLBI) provides funding to five Cell Processing Facilities (CPF) and a Coordinating Center (CC) in support of translational research, manufacture of cellular therapy products, and regulatory expertise to address all aspects of the translational and early pre-clinical and phase clinical development process.

PACT Program

PACT's objective is to promote the advancement of research in the use of cellular therapy in the regeneration of damaged/diseased tissues, organs, and biologic systems, and targeted treatments for serious diseases without effective therapies in support of the NHLBI mission. PACT supports translational and early phase clinical research of novel cell therapies. Successful clinical cell therapies require transformation of laboratory-based manufacturing and analytical techniques into specific cell production processing fulfilling regulatory safety and efficacy standards.

PACT will review requests for translational services with a goal of an IND submission, and clinical services in support of an existing IND, in the context of product development plan requirements.

PACT will consider applications for scientifically meritorious translational science research to progress along IND-enabling pathways. These activities include optimizing manufacturing processes, SOP development, CMC section development and cell manufacturing for use in relevant animal model studies. PACT will also consider supporting requests for clinical product manufacture for use in early phase clinical trials for disease treatment indications that are within NHLBI's programmatic scope.

PACT has the requisite expertise to provide regulatory assistance to investigators including gap analysis, guidance with FDA meetings, and review of meeting package materials.

Application Process

Investigators with scientifically meritorious and innovative ideas who do not possess the resources to manufacture products under cGMP/cGLP or are preparing for an IND submission and are in need of regulatory assistance are encouraged to apply to PACT. Investigators can apply for services by completing a Request for Services Application (RSA).

Information regarding the project scope, online RSA submission process, and criteria for evaluation, can be found on the website at **www.pactgroup.net**.

Review Process

The investigator must provide supporting information, including proof of concept, product characterization, and regulatory/developmental. RSAs will be reviewed by NHLBI to assess if the project meets the scope and review criteria for PACT:

- Cell products that aid in the repair and regeneration of damaged and diseased tissues, organs, and biologic systems
- Preclinical studies including basic and translational work
- Products and Services of programmatic interest to NHLBI
- Proposals possessing procedural advancements to further foster and standardize cell therapies

An external Scientific Review Board will review the RSA and provide scientific recommendation for NHLBI's consideration when determining final RSA approval.

Initiating PACT Services for Approved RSAs

When a regulatory RSA is approved, the PACT CC will contact the investigator to initiate regulatory services. When a clinical or translational RSA is approved, the NHLBI will solicit competitive proposals via a Task Order Request for Proposal (TORFP) from the PACT CPFs. The CPFs will bid to perform the work by submitting a task order proposal to NHLBI. NHLBI will evaluate proposals against the requirements of the TORFP and the award will be issued in accordance with the TORFP requirements. After award, technical and material transfer agreements between the designated PACT CPF and the investigator's institution/ organization will be negotiated. The investigator will communicate directly with the PACT CPF to finalize the services and production timeline. The project may proceed when an agreement is reached.