Resource Development
"Ask the Experts"
PACT Web Seminar
November 14, 2013

David H. McKenna, Jr., M.D.
Molecular & Cellular Therapeutics
University of Minnesota

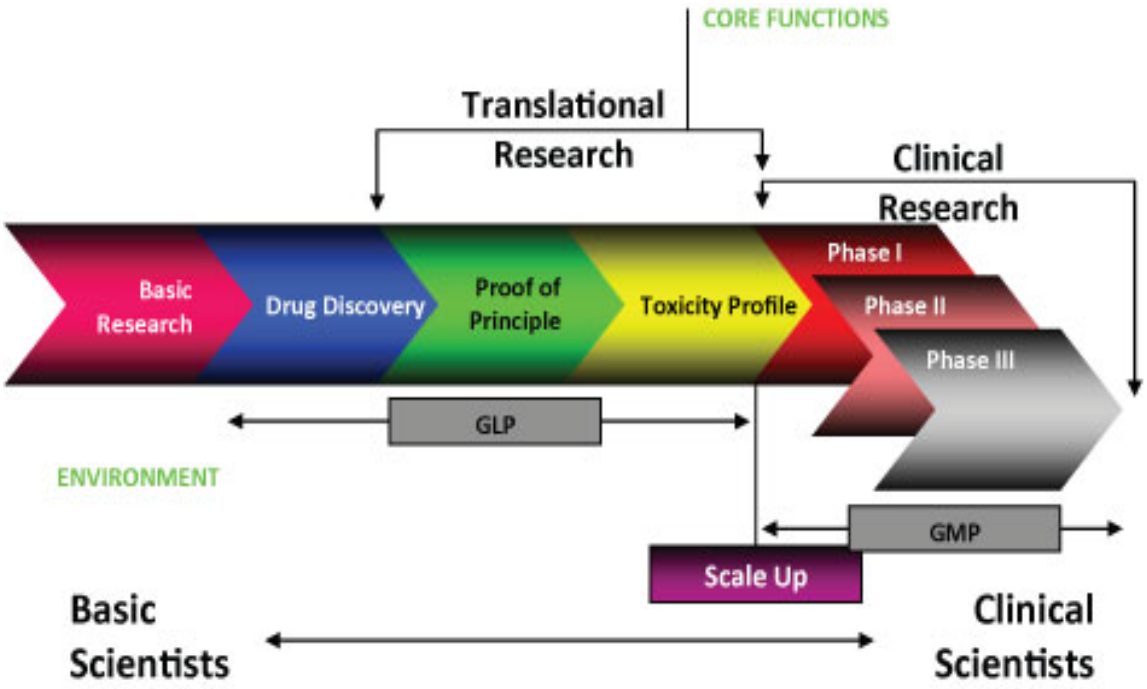
Molecular&Cellular Therapeutics
University of Minnesota

PACT
Production Assistance for Cellular Therapies
National Heart Lung and Blood Program

Objective

- Learn to develop a study **team** to coordinate the planning and initiation of preclinical and clinical research studies aimed at bringing the therapeutic candidate to the clinic

Overview



From Manual of Procedures, PACT Website

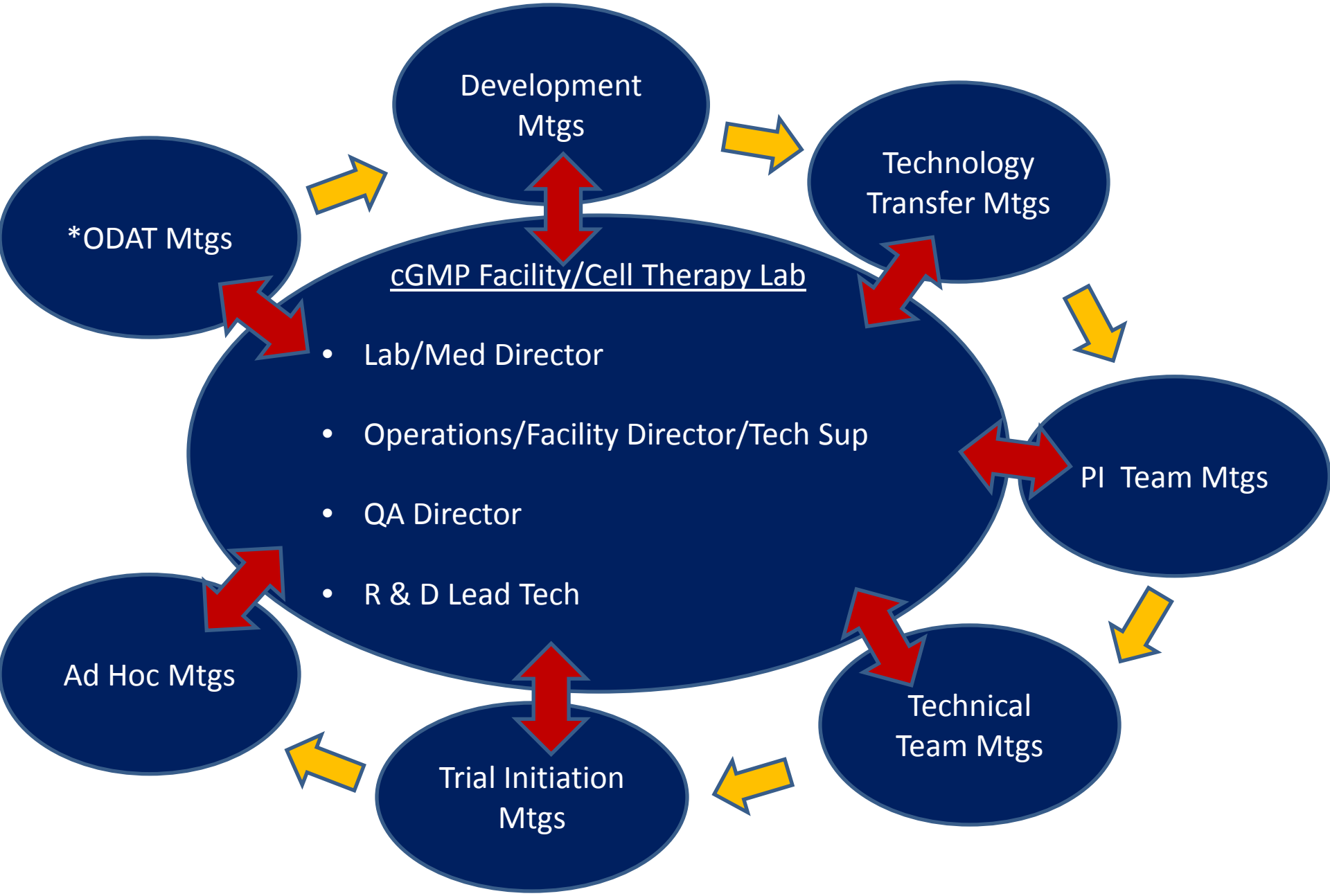
Perfect World

- Principal Investigator
- Clinical Research Team
- Project Manager
- Biostatistician
- Regulatory Expert(s)
- QA Expert(s)
- QC Expert(s)
- Technology Transfer/Product Development/cGMP Manufacturing Experts

From Study Team, Clinical Research Roadmap, Resource Center, PACT Website

Reality

- May be need to overlap expertise/responsibilities due to funds, logistics, institutional set-up, etc..
  - Project manager may be medical technologist
  - Biostatistician may be from institutional core
  - Regulatory expert may be QA Director
  - QC expert may be medical technologist independent of production
  - Tech transfer/product dev/cGMP manufacturing experts may be from other categories



ODAT = Office of Discovery & Translation, CTSI

Product Development Process

Minnesota Molecular and Cellular Therapeutics Facility (MMCT)
AcademicHealthCenter

Proposal

- Product Information
- Process Information
- Regulatory and Clinical Information
- Funding Information
- Contractual Considerations
- Intellectual Property

Assessment

- Opportunity and Strategy
- Clinical Requirements
- Regulatory Pathway
- Compliance Requirements
- Technology Requirements
- Space Requirements
- Contractual Issues
- Cost Estimates
- Biosafety Issues
- Facility Master File

Development

- Process
- Test Methods
- Supplies
- Equipment
- Clinical Strategy
- Documentation
- Budget
- Timeline
- Contract and Billing
- CMC
- Suppliers

Validation

- Timeline
- Validation Plan
- Documentation
- Training
- Test Methods
- Equipment Qualification
- Validation Report
- Validation Approval
- Risk Management
- Budget Review
- Facility Master Plan

Clinical Use

- Product Review
- CAPA
- Clinical Review (SAEs, outcomes)
- Regulatory Compliance
- Quality Monitors
- Financial Review
- Project Review
- Customer Satisfaction

Diane Kadidlo

Considerations

- When to involve cGMP facility/CT lab?
- How to approach technology transfer?
- How to cover costs of translation/validation/ clinical production?

Thank you!