MOLECULAR & CELLULAR THERAPEUTICS

Contract Development

Diane Kadidlo
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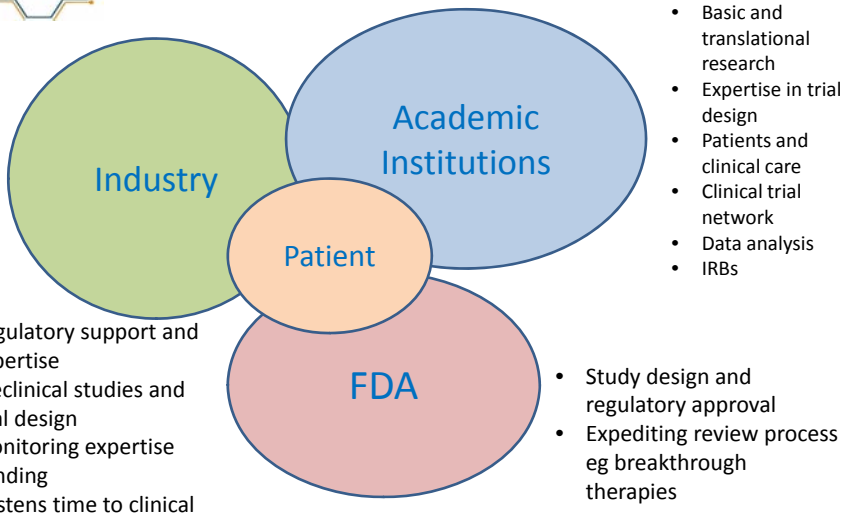
MOLECULAR & CELLULAR THERAPEUTICS
UNIVERSITY OF MINNESOTA
Driven to Discover℠

Partnerships



- Basic and translational research
- Expertise in trial design
- Patients and clinical care
- Clinical trial network
- Data analysis
- IRBs

- Regulatory support and expertise
- Preclinical studies and trial design
- Monitoring expertise
- Funding
- Hastens time to clinical trial

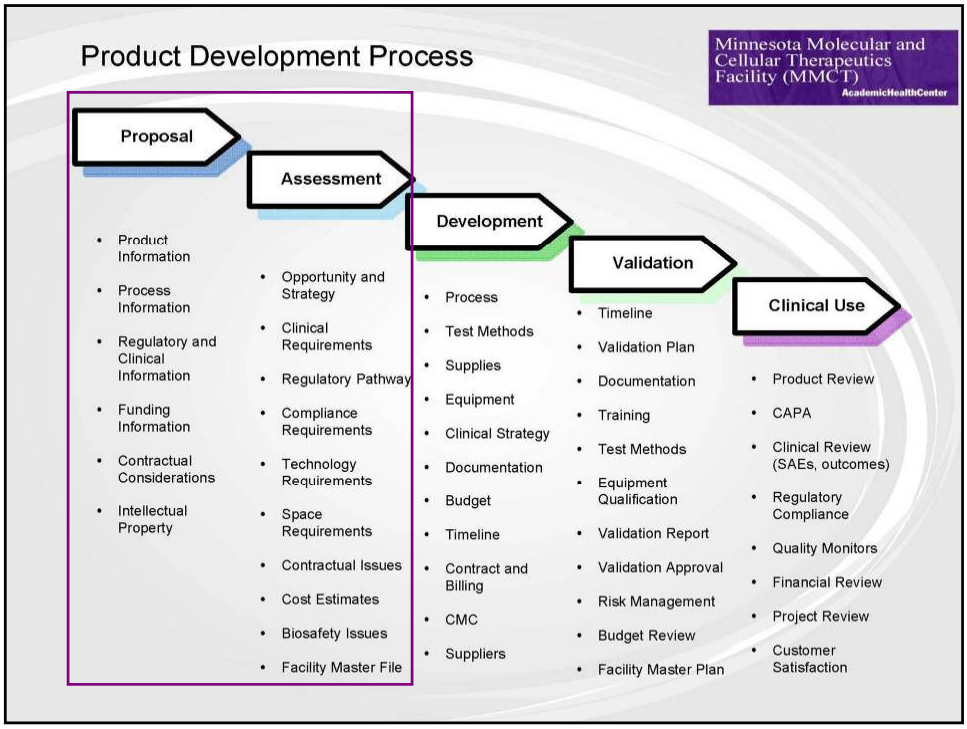
- Study design and regulatory approval
- Expediting review process eg breakthrough therapies

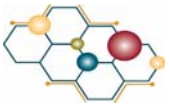
First Steps

- What are the expectations for the academic institution?
  - On site manufacturing
    - Product development
    - Validation
    - Clinical manufacturing of a fully developed product
  - Minimal to no site manufacturing
    - Collect
    - Receive
    - Infuse

Know Your Partner

- Vetting your industry partner
  - Scientific
    - Technical expertise
    - Publications
    - Clinical trial experience
  - Financial Status
  - Track Record





Project Evaluation

- Does it fit our mission?
- What are the unkowns?
  - How well is the product developed?
- What are the risks?
  - Inability to transfer technology
  - Meet development/production timelines
- Sufficient Resources
  - Staff
  - Space
  - Equipment
- Safety concerns

MCT PROPOSAL REVIEW	Assessment
Opportunity and Strategy	
Is the product feasible and consistent with our mission?	☐ Yes ☐ No
Is the scope, objective, and development path sufficiently clear to move ahead?	☐ Yes ☐ No
Time frame consistent with capabilities?	☐ Yes ☐ No
Have risks and assumptions been adequately defined?	☐ Yes ☐ No
Have adequate resources (infrastructure, human, space) been defined?	☐ Yes ☐ No
Clinical Requirements	
IRB Approval of Protocol	☐ Yes ☐ No
Regulatory and Compliance Requirements	
Has an IND been developed, submitted, and accepted? If yes, IND #_____	☐ Yes ☐ No
Is project consistent with FDA Establishment Registration?	☐ Yes ☐ No
Have risks associated with regulatory strategies been determined and has accountability for these risks been defined?	☐ Yes ☐ No
Define Clinical Trial Phase:	Phase I ☐ Phase II ☐ Phase I/II ☐ Phase III ☐
Will project impact Drug Master File?	☐ Yes ☐ No
Does this project require Drug Master File Revisions?	☐ Yes ☐ No
Technology Requirements	
Can a process be defined which will be reasonably expected to deliver product that will consistently meet the product specifications?	☐ Yes ☐ No

Contract Team

- PI
- Legal
- Finance
- CT Lab Administrator
- CT Medical Director
- Clinical coordinator
- Quality Assurance
- Contract Officer
- Office of Technology & Commercialization

CT Agreements

- Material Transfer Agreement
  - Transfer of biologics (cells, proteins, plasmids etc..), pharmaceuticals, data
- Research Agreement
  - Research and or Preclinical work --tech transfer, process develop, validation, tox studies
- Clinical Supply Agreement
  - Manufacturing of a clinical product not involving clinical trial on site.

CT Agreements

- Industry Sponsored Clinical Trials Agreement
  - Covers entire clinical trial patient, donor, product manufacturing, start-up, monitoring, PI effort
- External Sales
  - Exchange of product no research, no IP, no clinical trial on sight
- Quality Agreements
  - Agreements between manufacturer and sponsor relating to compliance and quality expectations

Material Transfer Agreements

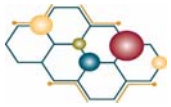
- Legal agreement for material that is transferred from one party (provider) to another party (recipient).
  - Biological materials (e.g., cultures, cell lines, plasmids, nucleotides, proteins, transgenic animals or plants, or pharmaceuticals), or information in various forms (e.g., data, databases, or computer source code).
- MTAs govern
  - Ownership of the transferred material and any of the modifications and derivatives made by the recipient;
  - Any limits on the recipient's use of the material and reimbursements for any costs of providing the material;
  - Protection of either institution from legal liability as a result of the use of the material by others;
  - Confidentiality of information relating to the material, and any issues regarding publications;
  - Rights to inventions and use of research results, including protection of related intellectual property rights or valuable know-how.
- Typically these are unfunded agreements whereby no money is exchanged

Contract Elements

- Project Scope
  - Statement of work – the overall goal
    - Research plan, process development, practice runs, validation, shipping studies, clinical trial
    - Define minimum number of experiments/ runs
    - Consider a phased approach especially in pre-clinical product optimization
- Confidentiality
  - A non-disclosure agreement (NDA) outlines confidential material, knowledge, or information that the parties
  - Separate or incorporated other agreements

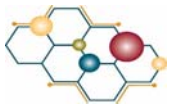
Agreement Elements

- Publicity and Publications
- Intellectual Property
  - Rights to technology, inventions, data, licensing
- Indemnification & Liabilities
- Representation & Warranties
- Regulatory compliance
- Budgets
- Timeline



Budget

- Budget
  - Supplies
  - QC Testing
  - Facility fees
  - Labor
    - Production
    - Document development (SOPs, protocols, validation)
    - Meetings/calls
    - Audits
    - Easily underestimated - Keep track of time



Budget & Timeline

- Budget for Failures
  - Incorporate language in the contract identifying the potential for failure and who is responsibility for cost
- Cost Reimbursement vs Fixed Pricing
  - Preclinical vs clinical manufacturing
- Timelines
  - Realistic
  - Establish milestones
  - Periodic review

Take Home

- Know your product
- Know the risks
- Build in flexibility
- Remember it's a Partnership