Industry Perceptions and Expectations of Academic Partnerships

David R. Parkinson, M.D.
President and CEO, Nodality
General Industry Context

• Developing new cancer therapeutics is slow, expensive, and risky
  – Complicated biology and heterogeneous disease entities
  – Difficulties in establishing POC, dose & schedule
• Many cancer therapeutics fail in later stages of development:
  – Risk management/decision-making issues
  – Opportunity costs
General Industry Context

• Novel biological therapeutics development has been particularly failure-prone:
  – Interleukins and interferons
  – Gene therapy
  – Differentiation therapy

• Successes, when they have been achieved, have been dramatic and continue to drive the process:
  – Monoclonal antibodies
  – Growth factors
Large and Small Molecule Drug Development: Differing Cultures

- Protein therapeutics potentially advantaged with respect to specificity of targeting
- More rapid agent creation in discovery
- Much slower commercial process development; issues with scale-up, product consistency
- COGS, stacking royalties, etc may affect decision-making, economic viability
- Biologicals often a product of academic labs, adopted for product development
- Historically these molecules have come from smaller, less-experienced biotech companies
- Greatly increased interest in biologicals from big Pharma in recent years: success examples, generics issue
Characteristics of Industry Sponsors

• Size, nature of the company may affect greatly the nature of investigator interactions

• Variables:
  – Depth of resources
  – Timeline tolerances
  – Milestone sensitivities
  – Available operational, project management and managerial expertise
Industry Expectations of Investigators

• Derive from the pressure on the sponsor: time, money, quality:
  – Scientifically-based:
    • Investigator expected to contribute expertise, observations, contribute to the thinking and learning about the agent
  – Clinical-based:
    • Contribution of well-treated, documented, evaluable pts
  – Regulatory constraints:
    • Regulatory compliance is non-negotiable
  – Contractual, IP, Technology Transfer issues:
    • Principles of reasonableness: physician fees, other requests
Where Conflicts Arise:

• When company and investigator expectations and/or performance differ............

• Institutional issues:
  – Contracts, IP, technology transfer

• Publication/recognition issues:
  – Timeliness of publication
  – Credit

• Performance issues:
  – Accrual, investigator cooperation, responsiveness, compliance, supervision

• Staff operational issues:
  – Company and institutional staff interactions
Some Advice......

• Never forget that responsibility to the patient comes first
• Meet all regulatory obligations
• Maintain your independence, autonomy as an independent clinical investigator
• Try to understand the company perspective while maintaining this independence
• Remember that conflict of interest can be both real and perceived
• Recognize that the best clinical research is a team effort, with contributions by many individuals
Academic/Industrial/Governmental Partnerships

• Successful examples:
  
  – DARPA
  
  – Sematech
  
  – SNP Consortium
Academic Expectations of These Partnerships: Advantages

• Industry as an additional source of:
  – Financial support
  – Technical resource e.g. formulation, production
  – Project-management of complex tasks
  – Support in regulatory interactions

• Industry as a mechanism to translate science into reality
  – Registration and commercialization
Academic Expectations of These Partnerships: Disadvantages

- Loss of control
- Ownership
- IP and technology transfer issues
- Recognition
- Financial issues
- Potential for conflict of interest/institutional complications
- Participatory rights
Industry Expectations of These Partnerships: Advantages

– Access to innovative ideas
– Access to expertise
– Potential new therapeutic agents, strategies
– Access to patients
– Opportunity to cooperate in new projects “offline” i.e. outside formal timelines, deliverables, investor scrutiny
Industry Expectations of These Partnerships: Disadvantages

- Loss of control; additional complexities
- IP issues
- Contractual issues
- Time-related issues
- Unrealistic financial expectations from academic partner
- Exposure risks: publicity, accountability, unanticipated governmental interactions
General Observations

• Cultural differences:
  – Differing reward and recognition systems; the role of the individual vs a team

• Behavioral differences:
  – Differences around timing of publication, privacy vs transparency issues, publication credit

• Common and differing agendas:
  – General goals more similar than different
  – Specific goals may differ: role of competition, time issues, etc.
Comment: Industry and Academia are not Homogeneous

• Variations in:
  – Academic institutions and corporate cultures
  – Investigator and corporate staff experience, expertise
  – Importance of external pressures
  – Importance of sensitivity to influence/interaction with various government agencies
Summary

• Academic/industry partnerships can combine the complementary strengths of each environment to solve complex problems
• The parties have similar and differing agendas, pressures, reward systems, expectations
• Successful partnerships require an understanding and accommodation of the needs of each participant