Industry Perceptions and Expectations of Academic Partnerships

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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 targetting
- 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 expections 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 accomodation of the needs of each participant