

# The “Win-Win” Collaborative Agreement

## Practical and Ethical Negotiating Strategies

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# The Thirty-Second Summary

- The ideal collaboration would not need a contract.



## The Thirty-Second Summary

- Handshakes are not enough, but neither are mere words on paper. If your partner perceives that its ultimate benefits don't properly reward its risks, you can bet on a breach and a lawsuit.





## The Thirty-Second Summary

- ❑❑ Handshakes are unrealistic, and you want to avoid litigation. This leaves only one sure route to successful collaboration:
- ❑❑ Full understanding of potential benefits
- ❑❑ Full appreciation of potential risks and costs
- ❑❑ Fair allocation of benefits, risks and costs



## Hypothetical Collaboration

- Partner A has a proprietary compound with anti-TNF properties
- Partner B has a novel topical delivery platform
- Collaboration goal: Topical formulation of Partner A's anti-TNF compound using Partner B's delivery technology
- A mutual CDA is already in place and each party has disclosed necessary information



## Understanding Your Prospective Partner

- Is your partner bigger, smaller or comparably sized?
- Extent of your partner's understanding regarding the market for the potential product/target
- Extent of your partner's experience in doing drug development (as opposed to discovery)
- Extent of your partner's prior experience with the particular science underlying the potential product
- How much authority does the negotiating team have?

## What Are Your Partner's Expectations?

- Why did they choose you (or do they know why you chose them)? What are their other options?
- What strategy is driving this deal for them?
- Do you share the same view of the collaboration's economic value?
- Do you share the same view of the value of each party's contribution?
- Does your partner expect to achieve some non-monetary benefit from the collaboration?



## Ethical Concerns/Confidential Information

- How many others have been approached and how far did the negotiations go?
- Does your partner have internal programs which could benefit from your confidential information?
- What are the risks if the negotiations do not result in a contract?



## Valuation Issues

- How much research has been completed (pre-clinical vs. clinical)?
- Can benchmarks be defined up front to test valuation?
- Is a preliminary feasibility study program appropriate prior to final contract?



## Parsing the Economics

- Financial Elements of the Contract
  - Research funding
  - Up front (license) fees (creditable or non-creditable)
  - Royalties
  - Milestones (Development or Sales)
- Front-end vs. Back-end compensation – who bears more risk in realizing value?



## Addressing the Intellectual Property Issues

- What IP does each party own?
- Who will own newly developed IP?
- Are there any CREATE Act issues?
- For new IP, who controls patent drafting, filing, maintenance, prosecution, defense?
- How are costs of new IP funded?



## Management of the Collaboration

- Do all decisions require consensus or does one party have veto power?
- Does the analysis change, depending on the phase of development?
  - Development Plan decisions
  - Commercialization Plan decisions
  - Co-Promotion (If Agreed)



## Addressing Performance Issues

- What are “commercially reasonable” efforts and “good scientific practice”?
- Dispute resolution mechanisms
- Consequences of declaring breach
  - Nature of breach
  - Effect on economics
  - Types of penalties
  - Ownership of IP, Regulatory Filings



## Modifying the Agreement

- Has the market changed significantly (new competitors, new products)?
- Has the product potential changed?
- Have the parties changed (takeovers, acquisitions, etc.)
- Must anticipate the unexpected – no agreement can deal with everything.

# Thank You



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