

Licensing Relationships

Licensing: Seizing Opportunities and Mitigating Risks

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Types of Relationships

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- **Naked License**
- **Assisted Tech Transfer License**
- **Cross-License**
- **Joint Venture**
- **Collaboration/Alliance**

Contexts

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- **University ↔ University**
- **University ↔ Industry**
- **Industry ↔ Industry**
- **Three or more parties**
- **International**

Common Issues

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- **Selection of licensee/alliance partner**
- **Setting goals & expectations**
- **Planning for & coping with market and technology uncertainties**
- **Management**
- **Dispute resolution**
- **Exchange of rights**
- **Sharing of expenses and rewards**
- **Restrictions on freedom (during & after)**
- **Termination & life after**
- **Legal constraints**

Collaboration Agreements & Alliances

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- **Core element of biotech world**
- **Multiple, inter-related collaborations are common**
- **Whole new dimensions of complexity**
 - **“Divorce” is common**
 - **High degree of uncertainty – re success, FDA approval, mobility of investigators/dependency on individuals**

Key Elements of Collaboration

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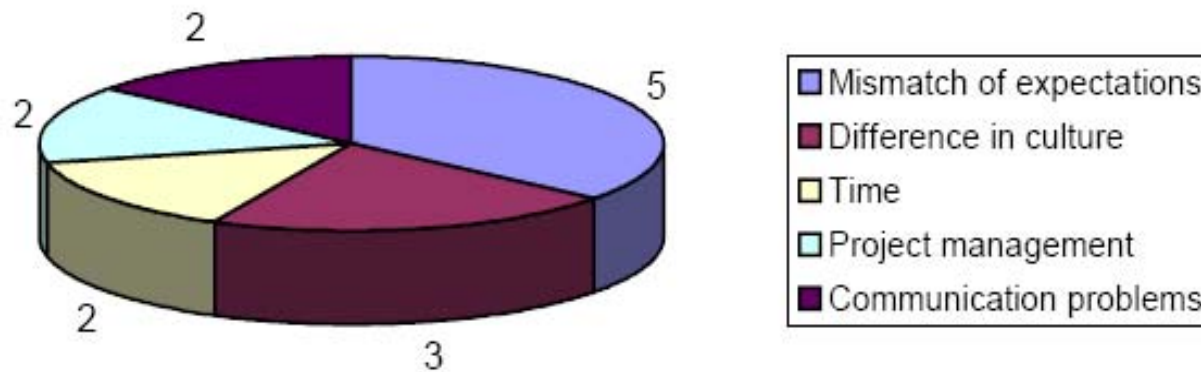
- **Proper planning**
- **Knowledge management**
- **Risk management**
- **Crisis management & dispute resolution (& termination)**
- **Proper planning**

Source: Veryard Associates

Failure

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- **Failure is common**
- **Study failure causes to improve chances for success and to plan to deal with failure if/when it occurs**



Source: website of the CREDO Lab: <http://www.vr.clemson.edu/credo/>

Alliance Failure Factors

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- **Overly optimistic**
- **Poor communications**
- **Lack of shared benefits**
- **Slow results or payback**
- **Lack of financial commitment**
- **Unclear operating principles**
- **Cultural mismatch**
- **Lack of alliance experience**
- **Alliance strategy**

Source: Dataquest data in *The Alliance Analyst*, based on survey of 455 CEOs, and reported at www.alliancestrategy.com.

Example #1

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Applied Biosystems and Illumina

“While it is unclear whether ABI acted maliciously or was merely unable to fulfill its obligation, the sour deal provides a cautionary example that small firms may find their research stifled when striking a deal with larger competitors.”

Preventing and Managing Collaboration Failure

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- **Planning for failure is one of important jobs lawyers do**
- **Distinguish from blocking deal**
- **Good planning actually may head off potential failure – or turn potentially monstrous failure into managed failure without dire results**

The Marriage Analogy

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- **Courtship**
- **Negotiation of pre-nup**
- **Marriage vows**
- **Marital reality**
- **Marital failure: (hopefully) amicable divorce or other dissolution**

The Courtship

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- **Ensure multi-level “buy-in” internally**
- **If possible, use same team for planning, diligence, negotiation, and implementation**
- **Know thy partner; understand partner’s philosophies, objectives, and strategies**
- **Make sure scope of deal is well-defined and equally well understood**
- **Principled (and cordial) contract negotiations**

From Courtship to Engagement

(i.e., From Negotiation to Relationship Mgmt)

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- **Prior to “kick-off” of alliance, reflect on/communicate to management team:**
 - **Goals of alliance**
 - **Key terms**
 - **Troubling terms**
 - **Quality of current relationship**
 - **Ways in which partners operate**
 - **Lessons learned to date**
 - **Potential challenges**
 - **Other relationships (of both parties) the alliance impacts**

From Courtship to Engagement *(cont)*

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- **Inform governance committees of their responsibilities**

Making the Marriage Work

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- **Raising the kids:**
 - **Steering Committee**
 - **Research Committee**
 - **Commercial Team**
- **Commitment of funds**
- **Identify “critical path” issues – e.g., relocation of PI to new organization or new project**
- **Compliance by employees**

Some marriages are more complicated than others

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Success Requires Solid Household Management

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- **How are functional responsibilities allocated between parties?**
- **Can essential purpose of alliance be met without formal governance structure?**
- **If governance committees are established, what are their respective functions?**
 - **Jurisdiction**
 - Substantive (*e.g.*, research, clinical, marketing, IP)
 - Geographic
 - **Discussion vs. decision-making**

Success Requires Solid Household Management *(cont)*

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- **Who sits on committees?**
 - **Functional team vs. executive management**
 - **Third party participation?**

Management Details Matter

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- **How do committees operate?**
 - **Frequency and location of meetings**
 - **Who is chair? What is her role?**
 - **How to change committee membership?**
 - **Can non-members participate? Under what circumstances?**
 - **Who pays for committee-related expenses?**

Management Details Matter *(cont)*

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- **What is decision-making process?**
 - Consensus vs. majority vote
 - Is that process consistent with internal processes of each partner?
- **How are decisions documented?**
- **What interaction between, or supervision of, certain committees is required?**

- **When it doesn't work out**

Termination and Survival Clause

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- **Defines the afterlife**



or



Business Clauses that Should Survive Termination

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- **Payment/refund**
- **Research results**
- **Intellectual property**
 - **Ownership/CREATE Act**
 - **Use by collaborator**
 - **Licensing to third parties**
 - **Revenue sharing**
- **Publication of results**
- **Dispute resolution**
- **Termination and survival clause**

Payment/Refund

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- **Sponsored research**
 - Payments typically upfront
 - Upon early termination, need refund of unexpended amounts
- **Joint or collaborative research**
 - Expenditures typically shared
 - Upon early termination, need final accounting of each party's expenditures and allocation of expenditures

Research Results

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- **Final research data and reports must be delivered**
- **If research continues past termination, final research data and reports must be delivered**

Intellectual Property/CREATE Act

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- **Allocation of ownership/ownership rules/
CREATE Act**
 - Rights to file patents
- **Internal use rights**
- **Option to license by sponsor/collaborator**
- **Rights to license third parties**
- **Revenue sharing**
 - From licenses to third parties
 - From use by collaborator

Intellectual Property/CREATE Act *(cont)*

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- **Licenses granted within collaboration agreement**
- **Materials**
 - **Return/destroy or continued use**

Publication

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- **Rights to review manuscripts prior to publication**

Dispute Resolution

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- **During collaboration**
- **Post collaboration**
- **Staged resolution**
 - **Negotiation**
 - **Required and time-limited**
 - **Can specify negotiators (e.g., presidents)**
 - **Can set up tiering of decision-makers**
 - **Mediation**
 - **Arbitration of all/specific issues**
 - **Define arbitrator/panel**
 - **Define procedures**

Dispute Resolution *(cont)*

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- **Each party may have veto/controlling vote in some realms – define precisely**
- **Define how voting is allocated**
- **Be very careful about delegating major decision to outsider – e.g., expert or arbitrator**

Final Thoughts

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- **Collaborations are like marriages**
- **Communication is key**
- **Prudence requires planning for divorce, other failures, and an afterlife**
- **Sometimes, good planning and execution can prevent divorce or disaster**