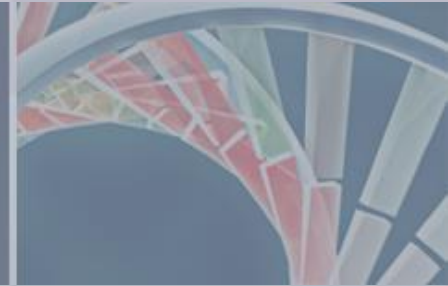




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A Proven Partner to the Life Sciences Community

Legal and Contracting Strategies That Maximize
Partnerships and Ensure a Successful Due
Diligence Process

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AGENDA

- I. **Due Diligence Requests: from Potential Partners and Investors:** What To Expect
- II. **Worst Case Scenarios for Life Science Companies**
- III. **Assessing and Mitigating Risks:** Formulation and Implementation of a Contract Management Strategy to Ensure A Smooth Due Diligence Process
- IV. **Favorable Contract Terms:** Which to fight for and which to concede
- V. **Final Thoughts**



I. DUE DILIGENCE: What Might A Potential Partner or Investor Request ?

Sample Due Diligence Request might read:

"This memorandum sets forth a proposed list of legal due diligence documents that should be collected as part of the due diligence process related to the [] (the "**Project**") and [] (the "**Company**").

As documents are collected, we are available to discuss the inapplicability of any requests and relevance of any information requested which may not be relevant to the business, operations, financial condition or prospects of a particular company. In addition, this list is extensive and relies heavily on the meaning of the term "material" in various contexts. As a general matter, unless this term is specifically defined below, something is *material* if:

1. **It is asset related;**

- (a) it has a replacement value exceeding \$[10] million ; or
- (b) it generates revenues of more than \$ [10] million per annum;

2. **It is liability related;**

- (a) the actual, future or contingent liability exceeds \$ [1] million;

3. **It is a contract, agreement, license or other document;**

- a) it relates to a material asset or liability; or
- b) it generates revenues or results in costs of more than \$ [1] million per annum;

4. **It is otherwise of particular significance to the business of the Company**, such as matters relating to significant intellectual property rights, change in control or non-competition issues.

Sample List of "Material" Contracts:

1. Copies of all material sale, supply, agency, distribution, franchising, advertising, licensing, royalty or similar agreements to which the is a party, including hereunder any manufacturing, sales and distribution agreements
2. A list of all agreements or arrangements that contain "change of control" clauses.
3. Copies of all joint venture and partnership agreements to which the Company is a party.
4. A description of any material research and development of technical co-operation or collaboration agreement.
5. Copies of any agreements or arrangements granting right of first refusal or other preferential purchase rights with respect to any material properties.
6. Copies of any confidentiality, secrecy or "non-compete" agreements with employees, customers, suppliers or others.

II. Preparing A Response: What Could Possibly Go Wrong?

- One realizes that there is no running "list" of expired and current contracts.
- Collaboration agreements have terms that are all across the board, you do not have an exclusive license to data you paid for and that used the only asset your company has.
- The clinical team agreed to a "bare bones" letter of intent, in order to expedite the process, with the CRO, paid 50% up front upon execution, and the company has yet to finalize an MSA.
- One discovers that some clinical or lab services agreements are expired, yet services are still being performed.
- It comes to light that some vendors do not have written contracts in place, but there is a suggestion that there may be signed terms and conditions around, someplace.

III. What Does a Proactive Due Diligence Strategy Look Like?

One can mitigate the risk of a poorly executed response to a due diligence request and craft and implement a contract management strategy by:

- Creating a “task force” and putting the proper internal stakeholders in charge of the process.
- Empowering each stakeholder equally and making them responsible for representing the interests of and ensuring the compliance of their respective functions.



“Diligence Task Force” End Game

The ideal end result would be:

1. A central location for a list of company contracts (a CMS system or an Excel spreadsheet) and a designated individual or an individual from each functional area whose job it is to enter and maintain data;
2. A sanctioned contract template library and contract terms that are consistent across all (i.e. same definitions for confidential info, assignment, etc.);
3. A clear mandate to use the company templates whenever possible;
4. One or more designated signatories appointed – no exceptions allowed; and
5. An internal or external resource dedicated to contract negotiation and finalization.



Notes on Contracting Strategy

Specifically charge the Task Force with ensuring:

1. Payments to Vendors ex-US:
 - a) Require written contracts;
 - b) Are only made to the named payee;
 - c) Are supported by detailed invoices, and;
 - d) CROs making payments on behalf of company are held to these same requirements.

2. Strategy is clearly communicated to all levels of the company



IV. Favorable Contract Terms To Insist on to Avoid the Tough Questions

A. Use of Data

- Never allow restrictions on the company's use of data, interim or final, that the company paid for or which was generated by use of a company asset / compound.
- Place reasonable restrictions on the vendor or clinical site's use of data – never go silent in an effort to avoid protracted negotiations.

Ideal "Rights to Data" text might read:

- All results, documents, data, know-how and formulas provided to the Institution and/or Principal Investigator for purposes of the Study or resulting from the Study ("Data") and Study Drug provided to the Institution and/or Principal Investigator for purposes of the Study shall be, are and will remain Sponsor's property and Sponsor will have the right to use the Data, including results of the Study, in any manner deemed appropriate to Sponsor's business interests.
- The Site will have the non-exclusive right to use Data from the Site for its internal Study patient care purposes and non-commercial, internal research purposes. Original medical records and source documents of Study patients are the property of Institution.



Favorable Contract Terms To Insist on to Avoid the Tough Questions (cont'd)

B. Confidentiality

- Ensure that the data generated in performance of the services is defined as being company confidential information – do not stop at designated as confidential information given by one party to another.
- Place reasonable restrictions on the other party's use of company confidential information (i.e. employees or need-to-know only)but do not agree to onerous obligations to keep the service provider's information confidential.

An ideal confidentiality clause might read:

"Any and all knowledge, know how, practices, process, data, or other information, including Data (hereinafter referred to as "Confidential Information") resulting from the Study or disclosed or submitted in writing or in other tangible form to the Institution and/or Principal Investigator, shall be received and maintained by the receiving party in strict confidence and not disclosed to any third party during the conduct of the Study and for ten (10) years thereafter. The Site further agrees to use the Confidential Information only for the purposes of this Agreement except as provided for herein. The Site may disclose Confidential information to the Study Personnel who require access thereto for the purposes of this Agreement provided that prior to making any such disclosures each such Study Personnel shall be bound by obligations to maintain Confidential Information in confidence and not to use such information for any purpose other than in accordance with the terms of this Agreement."



Favorable Contract Terms To Insist On To Avoid the Tough Questions (cont'd)

C. Assignment / Change of Control

- Agree only to terms that allow assignment without “prior written notice” and in no circumstances should one agree to “prior approval”.
- Envision oneself reviewing the clause from the point of view an party wishing to assume the contract.

Heavily negotiated, but acceptable, text might read:

“This Agreement shall be binding upon and inure to the benefit of Company and Service Provider and their respective successors and permitted assigns. Neither party may assign any of its rights or obligations under this Agreement to any party without the express, written consent of the other party, except that no consent shall be required in the case of a transfer to a wholly-owned subsidiary or transaction involving the merger, consolidation or sale of substantially all of the assets of the party seeking such assignment or transfer and the resulting entity assumes all the obligations under this Agreement.”



Final Thoughts

D. Other contract terms that may seem “immaterial” but can actually be very “material”:

1. Termination: Insist on some variation of termination for convenience and avoid hefty penalties for doing so.
2. Compensation:
 - a) Include an affirmative statement that all amounts paid are FMV and ensure that the budget actually is (ex-US especially).
 - b) Agree to payment terms that make it seem as if you know what you are doing (i.e. no 75% up front payments for software developers, etc.).
3. Intellectual Property:
 - a) Retain sole ownership of discoveries and inventions that arise in performance of the services as they relate to your drug, underlying data and data generated during the term.
 - b) Never agree to file patent applications for joint inventions, but ensure a ROFR to do so and get a ROFR to discoveries and inventions solely developed by the other party.



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