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# Clinical Research Collaborations: Practical Considerations for Israeli Life Sciences Companies

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**Dear Clients,**

For Israeli biotechnology, pharmaceutical, medical device and digital health companies, a collaboration with a leading hospital, investigator, technology transfer organization (TTO) or public funding body can be far more than a research project. It can generate early clinical evidence, open access to new patient populations or indications, build relationships with leading clinical centers and strengthen the company's story for investors, strategic partners and international markets.

That opportunity comes with an important qualification: the scientific success of a study does not necessarily translate into commercial value for the company that supported it. The outcome will often turn on whether the company has secured meaningful rights to the resulting data, inventions and follow on development opportunities, including rights held or administered by the relevant institution or TTO.

A recent JAMA Oncology study comparing federally and industry sponsored cancer clinical trials in the United States illustrates the distinct, yet complementary, roles that public and private research can play in the clinical research ecosystem (click here to read the study). For companies, the practical challenge is to translate promising findings into a viable development, regulatory and commercial pathway.

**Choosing the right collaboration model**

The starting point is deceptively simple: what role will the company actually play? It may sponsor the study, fund an investigator initiated study, supply investigational product without sponsoring the protocol, or enter a broader collaboration with an academic institution or hospital.

Each model brings a different balance of control, responsibility and access. A company sponsored study can offer greater influence over the protocol, data collection and regulatory strategy, but usually entails broader operational commitments and higher cost. An investigator initiated study may be a flexible, cost effective way to obtain initial clinical evidence, but only if the company's rights to data, study materials and resulting inventions are carefully defined.

The agreement should reflect the study's intended purpose. Is the objective exploratory research, support for a defined development program, data for regulatory use, evaluation of a new indication, or preparation for a future license or collaboration? The answer should drive the legal and commercial framework.

This question is particularly important when a company provides investigational product, funding or other support to an externally sponsored study. A recent systematic review of federally sponsored cancer clinical trials highlights both the potentially substantial cost of investigational drugs and the practical role of industry support in such studies (click here to read the systematic review). In this setting, the allocation of cost, product supply, data and intellectual property rights can determine whether the collaboration is feasible and whether it creates lasting value.

**Data: access is only the beginning**

Clinical data may be the collaboration's most valuable output. Companies should consider precisely what they will receive: raw data, patient level data where permitted, datasets, study reports, statistical analyses, safety information and regulatory correspondence.

Just as important is the right to use that data. The agreement may need to cover internal research and development, regulatory submissions, engagement with potential investors and commercial partners, due diligence, scientific publications and future clinical studies.

A right of access alone is not enough if the company cannot rely on the results for its intended purposes. The company should seek clear, sufficiently broad rights to use the data in developing and commercializing its products or technologies, subject to applicable privacy, ethics and regulatory requirements.

The analysis becomes more complex when data or materials are generated across multiple institutions, funded externally, or linked to digital health tools, diagnostic platforms or biospecimens. The company should identify every entity that controls or administers the relevant data and materials, including, where applicable, the institution's TTO and understand what approvals, restrictions or additional agreements may be needed for future use.

**Intellectual property: preserving the path to value**

Research collaborations can produce inventions, improvements, know how, clinical insights and new uses for existing technologies. The stakes are especially high when a study identifies a new patient population, combination treatment, biomarker strategy or therapeutic indication.

The agreement should clearly address ownership of pre existing intellectual property and intellectual property developed during the collaboration. If the institution or investigators may own new inventions, the company should consider an option, right of first negotiation, right of first refusal or another mechanism that preserves a credible route to a commercial license.

The company should also assess whether it needs rights to improvements of its technology, inventions that depend on its product or platform, and intellectual property developed using its confidential information or study materials.

Without these protections, the company may have enabled promising research, yet have no practical route to develop or commercialize its outcome. That gap can become highly visible in a financing round, licensing transaction or acquisition, when investors and prospective partners test the company's rights to the relevant data and technology.

**Publication, confidentiality and patent strategy**

Academic institutions and investigators have a legitimate interest in publishing study results. The objective is not to frustrate publication, but to ensure that publication does not compromise confidential information, patent protection or regulatory strategy.

The agreement should give the company advance notice of proposed publications and a reasonable review period, enough time to identify confidential information, request appropriate changes and, where needed, defer publication while patent applications are prepared and filed.

The parties should also agree on clear rules for public statements, press releases, conference abstracts and investor communications. This is particularly important where preliminary clinical findings are commercially sensitive or public disclosure could affect future patent filings, regulatory discussions or ongoing partnering negotiations.

**Building flexibility**

Clinical programs rarely proceed exactly as planned. Enrollment may slow, the protocol may need amendment, additional sites may be needed, or the company may want to explore a related patient population or indication.

The agreement should establish how changes will be approved and implemented, including amendments to the protocol, budget, timelines, study materials, clinical supply arrangements and each party's responsibilities. It should also address early termination, suspension, changes in the investigator's role and loss of funding.

Companies should plan for the end as well as the beginning. They should consider whether they will retain access to data and study materials if the collaboration ends early and secure

a workable transition mechanism if they wish to continue the study, launch a follow on study or transfer elements of the program to another institution or service provider.

**Due diligence starts with the research agreement**

A well structured research collaboration can materially enhance an Israeli life sciences company's development program. Clinical evidence generated by a leading academic institution or hospital may support investor discussions, strategic partnerships and licensing opportunities.

But investors, strategic partners and prospective acquirers will commonly examine the underlying agreements in due diligence. They will ask whether the company can access and use the data, whether a third party holds blocking intellectual property rights, whether publication rights are properly managed, and whether any third party has a claim on future commercial value.

Research collaboration agreements should therefore be viewed not only as operational documents, but as core building blocks of the company's financing, intellectual property and business development strategy.

**Six practical takeaways**

1. Determine the purpose of the study and select the appropriate collaboration model before negotiating the agreement.

2. Secure clear rights to access and use clinical data, study reports, analyses and related materials for development, regulatory, financing and commercial purposes.

3. Address ownership of existing and newly developed intellectual property, including a practical mechanism for obtaining rights to inventions that may be commercially relevant.

4. Establish publication and confidentiality provisions that preserve academic interests while protecting confidential information and patent opportunities.

5. Include flexible change control, termination and transition arrangements that support the potential evolution of the development program.

6. Review whether the agreement will withstand investor, partner or acquirer due diligence if the study generates promising results.

**Looking ahead**

Academic, investigator initiated and publicly funded studies can be powerful components of a broader clinical and commercial strategy. For Israeli life sciences companies, collaborations with local clinical and academic institutions may generate meaningful evidence, deepen clinical relationships and open new development pathways.

Ultimately, the value of the collaboration will depend not only on the quality of the science, but on whether the company has secured the contractual rights needed to use the data, protect relevant intellectual property and take the next step in development.

**The information provided in this client update is for general informational purposes only and should not be construed as legal advice or a substitute for professional legal counsel.**

**As always, the team at Agmon with Tulchinsky remains at your disposal.**

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