Building relationships

Industry leaders give their take on the ingredients needed for a successful pharmaceutical collaboration

Pharmaceutical collaborations take many forms depending on the participants, technology, market, stage of development, anticipated number of products, intellectual property landscape, internal complexity of the collaborators and the relative visibility of the deal. The relationship between the collaborators is one of the few elements within the control of the parties.

Successful collaborations stem from a strong relationship that is maintained over its lifecycle. Beginning with the early stages of the negotiation, the parties' representatives develop rapport and learn the diplomatic approach to navigating competing interests to balance the alignment of goals and incentives. Nothing compares to meeting in person with your counterpart and learning each other's style, risk tolerance, motivations, internal pressures and interests. The negotiation will be productive if there is transparency about needs, clear understanding of the internal decision making and gate-keeping process and active listening skills.

Often a kick-off meeting will help get the collaboration started on strong footing. The goal of the kick-off meeting is to build mutual trust and respect in each side's respective competencies, integrity and professionalism. In any relationship it takes time to develop personal chemistry between scientists and business contacts, but face-to-face interactions add considerably to this development. During the kick-off meeting one wants to gain a clear understanding of each side's decision-making processes. Although this may have been discussed in a preliminary manner in the negotiation, now that the agreement is signed, there will likely be more transparency.

Internal champions often become the relationship stewards for the collaboration. Those individuals are integral in developing alignment on the collaboration's success criteria, responding to unexpected developments, set-backs and opportunities that arise and garnering internal commitment. Internal champions may even co-locate during phases of the collaboration to oversee technology transfer and troubleshoot during the development process.

Knowing that it is possible for one side to lose its champion during the life of the collaboration, building many touch-points at various levels within the organisation around each side's champion will help ensure that it moves forward. To make inter-country collaboration successful is not enough to provide all terms of collaboration in the contract, it is also necessary to be really interested in the collaboration and to have "skin in the game". A good way to gauge and monitor the incentives of the parties is to establish collaboration success criteria and sales targets. An effective governance model is one more key factor for success, which may include several levels for communication between top management, managers and local personnel.

Some options for structuring people-centric governance models include:

- Procedures for sharing documents and tangible materials that can be implemented and are sustainable over the years.
- Regular meetings of the working groups representing the business, scientific and legal teams to discuss and monitor micro-level project management.
- Procedures to review meeting minutes on a regular basis to mark progress and identify early-on any need for re-direction.
- Quarterly in person meetings among senior leaders representing the business, scientific and legal teams to discuss macro-level project management issues.
- Annual in-person meetings of C-suite management to ensure continued commitment from the top and to avoid internal surprises.
- Detailed procedures to manage organisational changes, priority shifts, unforeseen market conditions and legal developments. These procedures may include mechanisms for legal landscaping and sharing of documents in a manner designed to preserve attorney/client privilege.
- Scaled dispute resolution processes to identify potential issues at a time when they may be addressed with the least impact on the outcome.

A strong relationship will lead to better outcomes, even if the collaboration fails for other reasons.

Pharmaceutical collaborations are often global in reach. A successful inter-country collaboration requires, *inter alia*, a clear understanding of variations in the cultures and the laws of different countries and possible ways to align them.

This rule is important for companies who want to start collaboration in any country worldwide and Russia and other Commonwealth of Independent States (CIS) countries are no exceptions. In particular, in order to start collaboration in the CIS region, as a first step it is essential to check local regulatory practice and industry standards in the CIS country. In general, the laws of many CIS countries in the pharma field are fairly formalistic and still require development, and the parties to the collaboration agreements often choose foreign law as governing the collaboration. Still, such choice of governing law does not exclude application of mandatory provision of local laws. For example, since under Russian law foreign law agreements must comply with mandatory

provisions of Russian law such as regulatory, competition, intellectual property, data protection and other law provisions, the parties must ensure that the collaboration agreement is in compliance with such provisions.

In relation to intellectual property laws, parties need to develop a process for ensuring during the collaboration that intellectual property rights are duly and timely registered in the respective territories. Each side may start the collaboration with background rights that are intended to be used or expanded upon during the collaboration. Due diligence will be important in determining whether the regulations have been complied with in each country of interest. With respect to patents, both mechanism of Eurasian patent registration and mechanism of patent registration via local patent and trademark offices (PTOs) are available in the majority of CIS countries. Also protection of trademarks may be sought in all the CIS countries on the basis of registrations with the local PTOs (with or without use of benefits of the Patent Cooperation Treaty) or on the basis of the Madrid Agreement and Protocol via WIPO.

There may be a good degree of familiarity with the patent office procedures that are standard in the US, including its electronic filing and reporting system, and in Europe. The countries of the CIS region may have less familiar bureaucracy. For example, the most common method of interaction with local state authorities in the CIS region is a written inquiry. Communication by email with local state authorities is not widespread. Furthermore, any documents/ inquiries addressed to state authorities should be originals or copies certified by a notary provided in the local language or together with a duly notarised translation into the local language. Any state fees need to be paid in advance and a confirmation of bank payment needs to be presented together with the relevant documents.

Navigating the legal landscape is not enough to ensure a successful inter-country collaboration. As with collaborations between companies in the same country, inter-country collaborations also require that the parties pay great attention to the details of anticipated collaboration and the personality of the partners. In particular, potential collaboration structure, regulatory specifics of products` development, manufacturing and distribution and partner`s reputation in the market need to be looked at.

Certain countries offer favourable treatment to companies incorporated in the region. This means, as an example, depending on the parties' preferences for market penetration, the parties may choose to form a corporate joint venture (JV) or contractual JV as an effective model. As to the regulatory specifics of research and potential manufacturing and distribution, in the CIS region for a product to be potentially distributed via the state procurement system, a state-owned company-business may be a natural choice. It is of course equally important to take into account the territory covered by the partner, the partner`s assets, facilities, labs, plants (if any), equipment, expertise, and so on.

The well-drafted termination clause is another cornerstone for any collaboration and the always spend time discussing and then 'memorialising' their plan of exit through all the various permeations. The plan for exit should, in particular, include:

- Termination of the agreement for all various permeations (failure to perform, impracticability of contract, and so on).
- Buy-out clause (usually included when one of the parties has stronger position in the market).
- Change of control.
- Enforcement of guarantee if included in the agreement.
- Force majeure procedures.
- Warranty claims and the effect of breach.

Though at the beginning of collaboration nobody wants to think of its end, it is very important to reach an agreement in relation to dispute resolution clauses. In order to increase a chance of amicable settlement, it is always advisable to include steps prior to litigation stages in the dispute resolution clause. Such stages may include senior management oversight, steering committees` chair casting vote, mediation and independent expert advice, and so on. In addition, traditionally, the parties covering the CIS area refer to arbitration as a way of resolution of disputes arising out of the agreement. This is due to the potential difficulties of enforcing the rulings of foreign state courts in the CIS area as opposed to enforcement of arbitration awards. Comfort with binding arbitration for businesses headquartered in the US and Europe is often is based on internal corporate policy. It is not uncommon that the arbitration clauses refer to international arbitration institutions such as WIPO, the London Court of International Arbitration and the International Chamber of Commerce.

The key factors for successful inter-country collaboration are the following:

- Correct choice of a business partner;
- Co-location to promote better understanding;
- Good technology and effective technology transfer;
- Intellectual property ownership protection;
- Well understood intellectual property legal landscape; and
- Agreed terms of dispute resolution and termination of an agreement

The awareness of the importance of the relationship is as important as knowledge of accepted practices and business laws and customs in the partner`s country. It is better to spend a bit of time investing in advance to minimise potential problems and disputes in future.

Authors




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