In a business as complex and high risk as drug development, successful deals are about collaboration. Some people mistakenly think of dealmaking as a way of extracting the most from your opponent, where getting to the ‘yes’ or the signed contract is the ultimate objective. However, this is rarely the case in the pharmaceutical industry, where closing the deal should be the start of a fruitful partnership. Being sensitive to setting the tone of the future relationship and reducing the impact of cultural barriers during the negotiation process are more relevant to delivering value to both companies (The Point of the Deal: How to Negotiate When ‘Yes’ is not Enough, Harvard Business School Press, Boston 2007). A culturally sensitive focus on implementation beyond executing an agreement makes the entire transaction process easier too.

Here, we focus on ‘closing the deal’ for pharmaceutical licensing and collaboration transactions, where two parties enter into a collaboration to move a drug or medical device program forward through development to launch, or to develop a platform technology. However, many of the points considered will be applicable to other types of deal, such as acquisitions and joint ventures.

Deals are about people
The deal team. For each external opportunity pursued, one of the first steps is to assemble a deal team. While some individuals will participate on multiple deal teams (specific functions such as legal, tax and finance that have individuals dedicated to transactions), it is unlikely that two deal teams will look the same except in very small companies. The core deal teams for both parties are those most engaged in the process to deliver the final signed agreement and implementation plans. To be successful, the core deal team members ideally need to possess all the necessary technical skill sets, including scientific and technical expertise relevant to the asset or program being licensed, financial expertise and legal expertise (Fig. 1).

It typically takes several months or even as long as a year or more to close a deal, especially when licensing or collaboration deals for which there is a lot of data to review and a range of issues to solve. Occasionally, deals can be closed quickly, with transactions completed in a matter of weeks. Transactions with shorter cycle times are not the norm, and tend to be large acquisitions, for which external competition may be high. Therefore, as with most long-term projects, attributes of the team members beyond their technical know-how impacts the outcome. Structuring a successful partnership that can be implemented effectively over the long term requires the development of a clear understanding of the needs and interests of stakeholders on both sides while simultaneously exhibiting cultural sensitivity. Thus, striving to build a team with diversity of thought, background, experiences and culture reduces the likelihood of misunderstandings throughout the transaction process.

Deal stakeholders. Equally important for long-term success is that the deal teams on each side continue to represent their respective organizations effectively by remaining as aligned as possible with the decision-makers and implementers. In smaller companies, stakeholders such as the CEO or CSO may be part of the deal team or be instantly accessible, which delivers rapid decision-making during negotiation. Larger organizations may move more slowly, and often have specific governance structures designed to ensure organizational alignment. For multinational pharma companies, experts throughout the enterprise may be consulted to ensure that implementation of the proposed deal is feasible (Fig. 1), and it is not unusual to have more than 50 cross-functional stakeholders reviewing the first draft of the contract. It is recommended that both parties understand the governance and decision-making process for the transaction on both sides in advance of starting detailed negotiations.

Cultural sensitivity. Cultural differences between countries and regions are expected, and these of course apply to biotech and pharma deals. Perhaps less immediately obvious are divergent social norms in different organizations even within the same background culture. Keeping an open mind and understanding whether an apparent misalignment of values or requirements is a real business issue or a cultural difference is important.

Designing the deal
Value creation. The primary purpose of doing a deal is to create a multiplicative effect, by combining the strengths of both parties in the best way so that 1 + 1 = 3. Designing a successful collaboration also requires development of a mechanism to share the risks and rewards between the parties so that both feel that they have arrived at an equitable balance and can ‘sell’ the deal to their respective boards or owners.

Thus, the likelihood of closing the best possible deal increases if you focus on creating value before you start claiming value. Deepak Malhotra and Max Bazerman of Harvard Business School stress the importance of avoiding the ‘fixed pie bias’ and instead focus on growing the pie before you start dividing the pie (Negotiation Genius, Bantam Dell, New York 2007). Even if you get a slightly smaller piece of a larger pie, the trade-off may be significantly more profitable for your company. If you focus too much of your energy on claiming value, it will be easy to miss opportunities to create value throughout the deal-making process. While it is important to find areas of common ground in any negotiation, identifying the areas where the companies have
differences can unlock tremendous value in negotiations. The objective of your negotiation should be to create, and then claim, as much value for the long term as possible. This will increase the likelihood of closing a deal that will be successfully implemented by both parties.

**Focus on interests, not issues.** Defining what is most important to each party and why, is a critical step in reaching alignment. One of the biggest mistakes one can make during deal development and negotiation is to focus only on individual issues or demands made by each party. You will greatly increase your odds of closing the deal by focusing instead on the underlying interests of each party. As you come to understand what is most important to each party (for example, cash flow in the near term, total deal economics or exclusivity), it is equally important to understand why each item is important. By understanding the underlying interests of both your company and the other company, the door will be open to much more creative deal design options and solutions throughout the negotiation.

**Firewalls and confidentiality.** During the deal process, both parties will execute a confidential disclosure agreement (CDA) or non-disclosure agreement (NDA) to enable sharing of confidential information. Typically, the information shared can be used only to evaluate the deal and facilitate the transaction. If the deal does not close, neither company can use what they have shared for any other purposes. For this reason, the deal process becomes more complicated if both parties are working on the same type of program. Particular care must be taken to avoid exposing individuals not involved in the deal process. More often than not, the technical experts working on the internal program have no idea that business development is involved in the deal process. More often than not, the technical experts working on the internal program have no idea that business development is exploring a potential deal for a similar program.

**Aligning value with risk reduction—value inflection points.** Product licensing or collaboration deals in pharma very rarely involve a simple up-front payment. Because the programs involved typically have a relatively low probability of technical success (that is, reaching the market), payments are commonly aligned to events where specific risks have been discharged, such as proof of concept in phase 2 trials. Therefore, a very important part of structuring a deal that contains contingent payments is determining which inflection points provide the most important data and/or discharge the risk associated with future product development. These events are unique to the specific program and the types of risks it presents. A first-in-class program addressing a completely novel pathway in a disease with no current therapeutic options will have a very different development trajectory to a best-in-class molecule in a well-understood indication. Furthermore, the list of critical risks, and the studies needed to address those risks may evolve once a deeper technical due diligence is completed. This underscores why it is important for the core deal team to include members with in-depth technical scientific expertise as well as financial expertise to ensure that as the deal structure evolves during negotiations, the payments remain appropriately aligned with inflection points that reduce risk.

**Refining the deal**

Once the broad outline of the deal and what each party wants to achieve are understood, who does what needs to be decided, which party will be responsible for each component of the program going forward and who will manage the financial arrangements. As a general rule, the more complex the arrangements, the longer the deal will take to develop and negotiate.

These arrangements are then refined based on the results of detailed due diligence. The objective of the due diligence is to verify the claims made by the originating party, but also to inform and refine the business case by reviewing the risks and establishing an independent view of the critical value inflection points, probable launch date and costs of development. This in turn will refine and shape the final deal structure and inform which areas of the deal may need particular attention during contracting.

**Non-binding offer.** For the majority of deal types, proposed deal terms will be formally communicated in the form of a non-binding offer (NBO), which can also be referred to as a term sheet or indication of interest. The NBO provides a format whereby both parties can easily share the material deal terms with stakeholders and ensure alignment before either party invests more resources into exploring the transaction. Items that will have material financial, operational or development impact on the programs contemplated in the deal are included in the NBO. For pharmaceutical assets, terms will often include financials, decision rights and governance, details of product development. These events are unique to the specific program and the types of risks it presents. A first-in-class program addressing a completely novel pathway in a disease with no current therapeutic options will have a very different development trajectory to a best-in-class molecule in a well-understood indication. Furthermore, the list of critical risks, and the studies needed to address those risks may evolve once a deeper technical due diligence is completed. This underscores why it is important for the core deal team to include members with in-depth technical scientific expertise as well as financial expertise to ensure that as the deal structure evolves during negotiations, the payments remain appropriately aligned with inflection points that reduce risk.

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development (such as roles and responsibilities, indications and formulations), details on product commercialization (such as roles, responsibilities and geographies) and intellectual property.

One complex concept frequently discussed as part of potential deals but rarely seen incorporated is splitting product indications, where both parties assume development and/or commercial responsibilities for the same molecule but for different indications. Splitting indications is difficult, as it has important operational implications and risks. All clinical outcomes (positive and negative) will likely be applied across all indications. Generally, a single safety database will need to be maintained by one of the parties. Regulatory requirements and actions will also apply equally. The Lilly team have found it particularly challenging to structure deals that allow for commercialization of separate indications by separate companies. In most countries, sales reporting systems do not capture product sales in a manner that makes this concept feasible.

**Scientific due diligence.** For most pharmaceutical assets or platform technologies, a full scientific due diligence will be required before a deal with large up-front or near-term payments is signed. Smaller deals may require a less rigorous due diligence process. Due diligence typically involves a team of subject-matter experts reviewing all existing data and plans for future work developed by the originator. The due diligence team also generally develop their own version of a detailed plan for progressing the molecule toward an eventual launch or applying the platform technology in the context of the receiving company’s portfolio.

Selecting your due diligence team members is an important part of the deal process. If the deal contemplates a drug development program that is in clinical development, the team can be upwards of 30 people. You will get much better results if the individuals selected have a problem-solving mindset along with the knowledge necessary to assess quality and probability of success.

**Corporate due diligence.** If the deal involves the acquisition of a company or taking an equity stake or ownership position in the company, full corporate due diligence will also likely be required. Corporate due diligence seeks to understand the value and risk associated with the whole company, not just the asset or the platform. The investing company will likely require review of documents such as company financials, material contracts, human resource documents, ethics and compliance programs, and all other legal documents necessary to accurately assess the enterprise value today and the potential for additional value creation after closing the deal.

**Intellectual property assessment.** Intellectual property (IP) is one of the most critical components of a pharmaceutical asset transaction. IP is often intangible and can be comprised of many things, often including patents, know-how, trade secrets and other proprietary information without which there would be no transaction. For a deeper consideration of this topic, see the previous article in the series (Protecting biotech IP to support deal value: BioPharma Dealmakers, B2-B4, June 2019).

An in-depth assessment of IP can take considerable resources and time, often requiring consultation with external legal counsel, so be thoughtful about when to sequence this assessment for each transaction. When a transaction contemplates IP with multiple owners or IP that has changed hands in the past, the assessment will be even more complex. It is not uncommon for pharmaceutical assets to change hands multiple times over the 20 or more years between discovery and commercialization (A year in biopharma dealmaking. BioPharma Dealmakers, B29-B31, June 2019).

**Signing the deal**

Ideally you have gained alignment between both parties on the material and potentially contentious points of negotiation during the term sheet phase. If both parties understand their own and the other party’s interests, transitioning those concepts from a short (usually ten pages or less) NBO document to contracts (usually 100 pages or more) will be much easier. Contract development on average takes at least 2 weeks. But the negotiation process can be much longer, especially if the deal is complex, and in rare cases takes more than 2 years if other factors intervene. In this section, some of the business concepts that tend to take more time than others are addressed.

**Co-development.** Co-development can mean the partners each take practical responsibility for different parts of the development program or alternatively that the parties split the cost. For small companies, active participation in development often seems an attractive opportunity to learn from an experienced partner. Deal teams need to balance this desire with the risks associated with the increased complexity. As operations and decision-making increases in complexity, it is difficult to avoid a corresponding decrease in the speed and increase in the cost of development, thus eroding some of the potential value created through the deal.

**Handling IP and know-how during a partnership.** Assessment of existing IP is part of due diligence, and further examination will likely be required during contracting. It is critically important that both parties contemplate the ownership and use of new IP generated as a result of the deal (often referred to as foreground IP; as opposed to the background IP; which the two parties contributed at the start of the collaboration). Inventions or improvements directly related to the program are often treated as joint IP. However, new IP may be generated while developing an asset that is not specific to the asset in question, and deciding how this will be handled can quickly create considerable complexity in the deal. One example is a new general manufacturing process that employees of the receiving party invent in the course of their work and seek to apply to all assets in their portfolio. Another example in platform deals is consideration of how data generated during the collaboration can be used in artificial intelligence or machine learning environments.

The confidential know-how of both parties is often less quantifiable but can be equally important to the eventual success of a product or process. Some consideration of how to ensure critical know-how is preserved in case of staff turnover or one party being acquired or entering into arrangements with others in a separate transaction will likely need to be included as part of the contract.

**Look beyond signing to successful implementation.** More often than not, the individuals most active in the deal process are not those who will be implementing the deal post-signature. For the confidentiality reasons discussed earlier, the teams who will implement may not even be aware of the deal until after it has been signed. It is important for the deal team to effectively transition the program to the implementation team. Even among large pharma companies, the process for alliance management differs. Some have the capabilities in-house, some outsource their alliance management functions, and some have leadership for implementation reside within the various business or functional units. At Eli Lilly, experience has shown that having the deal team dedicate time to this transition results in much faster and smoother implementation of the deals.

**In conclusion**

Closing the deal is more of an art than a science, even for the most seasoned dealmakers. Successful deals require coordination and collaboration throughout the process. The best deals create value for both parties, where there is alignment both in the spirit and the letter of the deal. Cultural fit is also important and can be built and improved upon during deal process by focus on implementation beyond deal-signing. As a general rule, the more complex the arrangements, the longer the deal will take to develop and negotiate. The most successful deals are those where both parties feel they have achieved an equitable sharing of risk and reward and both sides feel like winners.


"The primary purpose of doing a deal is to create a multiplicative effect, by combining the strengths of both parties in the best way so that 1 + 1 = 3."