# The key to successful collaborations: Rigorous and independent due diligence

*Ian Rhodes, Craig Nelson and Gregory Berman*

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**Ian Rhodes**
is a member of PA Consulting's Management Group and has worked exclusively in the Healthcare and Life Science sector over the past 15 years, specialising in market assessment, technology assessment and technology strategy. Ian has written Experts Reports for London Stock Exchange listings for many companies and provided input to a number of due diligence assignments.

**Craig Nelson**
is a Managing Consultant within PA Consulting Group's Global Technology Group where he specialises in market assessment, technology assessment and technology strategy in a range of industries. Prior to joining PA, he worked in research and development on optical systems.

**Gregory Berman**
is a Managing Consultant and leads PA's Medical Products Group at its Cambridge Technology Centre. He has spent the last 15 years working across the spectrum from strategy to technology development and exploitation; helping companies to manage, evaluate and commercialise healthcare technologies in order to extract maximum value.

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Ian Rhodes
PA Consulting Group,
Cambridge Technology Centre,
Melbourn SG8 6DP, UK

Tel: +44 (0)1763 267492
E-mail:
innovation@paconsulting.com

## Abstract

In a maturing bio-pharma industry and with capital markets closed, collaboration is becoming the main route for companies to achieve the critical mass and cash flow necessary for sustainability. Indeed, collaboration is currently being driven by several factors, including the high-risk/high-reward profile of drug development, the lengthy time to profitability and the credibility provided by big pharma backing. However, in a complex industry such as biopharmaceuticals, many collaborative deals fail to deliver the value they initially promise. In this environment rigorous and independent due diligence will pay handsome returns by minimising 'asymmetry of information', and will allow companies to structure more successful deals, with risks and rewards more fully understood. How can state-of-the-art due diligence processes help clarify the objectives, define the optimum deal structure, identify the right partner and provide a pragmatic strategic plan to improve the chances of successful collaboration?

## INTRODUCTION

The biotechnology industry is maturing. This is demonstrated by the increasing number of new biotechnology product approvals (up from 19 in 1997 to 35 in 2002[1]), and the increasing number of biopharmaceutical companies achieving profitability. The business environment for biotechnology companies is also changing:

- The capital markets are all but closed, making it difficult for small to medium sized biotechnology companies to raise money through flotation on an appropriate exchange.
- Capital markets have become wary of the risks inherent in the biotechnology sector following the under-performance of previous biotechnology companies coming to the market.
- There is an increasing 'funding gap' between the relatively low levels of start-up finance provided by 'business angels' and the few millions provided by venture capital firms (VCs). Typically VCs prefer to commit funds to a smaller number of large and more mature investments, so that obtaining modest levels of VC funding can often become problematic.
- The increasing realisation that the cost of developing new biotechnology products is high and inherently risky.

The concatenation of these factors means that collaboration within the industry is becoming more and more essential to allow biotechnology companies to survive and grow. The extent of this collaboration can be seen in the results of a recent study[2] of the ten largest pharmaceutical companies, in which the gross revenue generated from in-licensed compounds grew from 24 per cent of the total in 1992 to 35 per cent in 2000, and was projected to reach 45 per cent by 2002.

## WHY COLLABORATE?

**Collaboration can provide significant value and benefits to both parties**

Collaboration between biotechnology companies and large pharmaceutical companies has the potential to create benefits and value for both parties. For small biotechnology companies with relatively few employees (and few biotechnology companies have more than 100 employees) collaboration with large pharmaceutical companies has a number of potential benefits. These include access to:

- the financial resources of the large pharmaceutical company;
- the regulatory experience and infrastructure of the partner;
- extended development resources to develop emerging products;
- the sales and marketing capability of the large pharmaceutical company;
- the credibility and perceived value provided by working with a mature and respected organisation.

Equally, the biotechnology company can provide significant benefits to a large pharmaceutical company through collaboration, including:

- supplying new products to fill the requirement for a healthy product pipeline;
- providing access to new technology to assist in drug discovery or development;
- exposure to a more nimble, innovative and radical culture.

## BIOTECHNOLOGY COMPANY ISSUES

**The development of new biotechnology products for treatment of disease is highly capital intensive**

The development of new biotechnology products for human pharmaceuticals is highly capital intensive. It has been estimated that it costs at least £300m to bring a new drug to the market.[3] British Biotech has spent ~£170m on overall development costs and is still some way from marketing its first drug. These sums are potentially prohibitive to a small biotechnology company without the financial muscle of a large pharmaceutical company, in the absence of available public capital. It can take up to 10 years to develop a new drug, but it is not clear until after the later stages of clinical trials whether or not the product will be a success. This means that substantial capital investment will be required before it is known if the product will work and hence generate revenues. The risk profile for drug compound development is therefore heavily back-end loaded. Parallels have been drawn with the petrochemical industry where many millions can be spent researching and drilling a new well, without knowing if any oil can ultimately be extracted.

**The risk profile for pharmaceutical drug development is heavily back-end loaded**

Even if money is available for development of the product, the company needs to be sure there is a market that is big enough to provide an attractive return on the investment. The company also needs to ensure that its technology or product will not be overtaken or replaced by that of a competitor.

The industry is also subject to high levels of regulation. For example, the New Drug Application (NDA) for Ziconotide was 750 volumes in length, containing 300,000 pages. Small biotechnology companies rarely possess the expertise and resources to operate with the rigour required to satisfy the regulatory authorities and to generate and maintain the appropriate level of documentation required.

The research and development resources required to characterise, develop and formulate new drug products are also substantial. The production of a new biotechnology-based molecule is only the first step in developing the final formulated product. This requires experience and resources not often readily available to most biotechnology companies.

Finally, in order to market a new drug successfully the biotechnology organisation will need access to a sales and marketing organisation with the experience and correct infrastructure to understand and exploit the market potential of a new compound.

**Biotech companies can be grouped into those with financial resources and these with promising leads – few companies have both**

There are, of course, related drivers for biotech-to-biotech collaboration. The majority of biotechnology companies can be grouped into those that possess significant financial resources and those that possess promising science or leads – few companies have both. This provides further opportunities and incentives for biotechnology companies to collaborate effectively and generate synergistic benefits through partnerships.

In summary, the requirements of both parties strongly suggest that collaboration is a key trend, and indeed the number of partnerships within European biotechnology companies rose from 216 in 1996 to 539 in 2000.[4] This trend is likely to continue to grow as companies realise the importance of establishing strong networks of collaborative activity.

## HOW CAN ORGANISATIONS INCREASE THE CHANCES OF COLLABORATION BEING SUCCESSFUL?

While the drivers for collaboration are clear, success can never be guaranteed. There are many common pitfalls[5] associated with collaboration, including:

**ImClone's share price collapsed after the FDA turned down their application for a BLA**

- lack of an executive champion;
- no implementation of the post-deal strategy;
- poor integration of systems and culture;
- unrealistic expectations by either party;
- lack of well-defined metrics for success and failure;
- resistance to change;
- lack of communication.

The effect of these issues is often critical, and many examples exist of failed collaborations within the industry.

For example, IGEN International is involved in a long-running legal dispute with Swiss pharmaceuticals group Roche Holdings over the licensing of IGEN's blood-testing technology. This technology was originally licensed by Boehringer Mannheim, who were themselves acquired by Roche. The companies have been contesting claims since 1997 that agreements covering the marketing of the technology have been breached. In 2002 a Maryland jury awarded Igen over US$500m in damages. Although Roche is appealing against the verdict analysts confirm that the decision was a significant blow for Roche, and one that could have been avoided by a more thorough due diligence process.

But perhaps the clearest example is the recent failure of the partnership between BMS and ImClone Systems. In 2001 BMS entered into a remarkable US$2bn deal with ImClone Systems to develop and commercialise a novel antibody-based therapy, with BMS taking a 20 per cent stake in its partner. However three months later the FDA turned down ImClone's application for a Biologics Licensing Application (BLA), submitted with only limited Phase II data. The fall in ImClone's share price resulted in BMS writing off US$735m of its investment, and led to shareholders filing lawsuits claiming that the company had made false statements about the prospects of the drug. Moreover these allegations have led to congressional enquiries and investigations by the Securities Exchange Commission (SEC). The thrust of many complaints was that BMS had poorly researched ImClone before investing. Clearly BMS was unaware of the issues surrounding its partner's licensing application, and its response to the setback was an attempt to restructure the original

deal. Arguably better due diligence would have uncovered the key issues, and led to a better deal that would have enabled both parties to derive value from the collaboration.

Both of these collaborations have cost the respective partners dearly, and many of the problems could clearly have been avoided by a more thorough due diligence process.

In order to succeed in collaboration, the key steps within the process should be planned and executed with the correct team of internal champions and experienced advisors. The key steps for the collaboration process are outlined below:

**Many companies have established collaborations without understanding the strategic drivers**

- Definition of collaboration strategy – document drivers and desired outcomes.
- Identification of potential partners.
- Evaluation of potential partners – due diligence.
- Deal structure – including building and agreeing the post-deal Implementation Plan.
- Post-deal value creation – Implementation Plan executed.
- Measurement of performance.

## COLLABORATION STRATEGY

**Collaboration should only be undertaken after understanding how it can add to the organisation**

Collaboration, like any partnership, should not be undertaken without first understanding the reasons for considering why it might add value to the organisation. We explored earlier the reasons for collaboration, such as access to technology, filling the product pipeline, innovation culture and access to markets, finance and regulatory support. Clear criteria should be set at this stage to help assess financial risk, technology areas and markets to be addressed, and these should be reviewed to ensure they are aligned with the overall strategy of the organisation. When these have been defined, agreed and documented, the search for suitable partners can begin.

## IDENTIFICATION OF POTENTIAL PARTNERS

When the collaboration strategy has been set, this should direct the search for appropriate developments and potential partners. A number of sources of information can be used to identify potential partners including:

- industry knowledge;
- conferences;
- investment banks;
- industry journals;
- individual networks;
- consultants.

This should be established as a defined project with an internal champion from inside the organisation. Doing this without commitment or as a spare-time activity is a certain recipe for disaster. The search will typically generate a large number of potential partners, technologies and market segments. The criteria developed as part of the strategy definition should be used rigorously to filter the list to the most promising options. The process of partner identification should not be undertaken opportunistically. Timely opportunities can be exploited but they must always fulfil the criteria defined within the operational strategy. There are many examples of companies that have entered into collaborations without fully understanding how the partnerships will meet the strategic intent. Not only do these collaborations often fail to deliver value to the companies concerned, but also the time and resource-consuming nature of the partnership can have a significant and deleterious impact.

## DUE DILIGENCE

**Thorough and detailed due diligence is critical to successful collaboration**

When a suitable candidate has been identified, it is critically important that thorough and detailed due diligence should be carried out on the potential partner. This process is not just about confirming the status of the technology and financial status of the potential partner (although these of course must be covered). If carried out correctly, this process has the potential to:

- define the future plans for the collaboration;
- set metrics for the collaboration;
- identify key areas of risk, and suggest actions to address them;
- benchmark an organisation against industry best practice;
- provide the basis for a deal that will balance the needs of all partners;
- bring the two parties together in a way that avoids surprises at a later date;
- encourage the two parties to have more challenging and difficult conversations earlier in the relationship, rather than having these issues surface at a later date;
- increase the overall chances of success for the collaboration.

**Due diligence is all about reducing risk through collecting relevant information**

Due diligence is primarily about collecting and analysing information to reduce risk in the transaction. Technical due diligence should therefore seek to answer a number of key questions such as those outlined schematically in Figure 1.

The due diligence team should have the experience to cover all aspects of the operation, including:

- commercial;
- products;
- intellectual property;
- clinical development;
- regulatory issues;
- operations;
- management;
- financial;

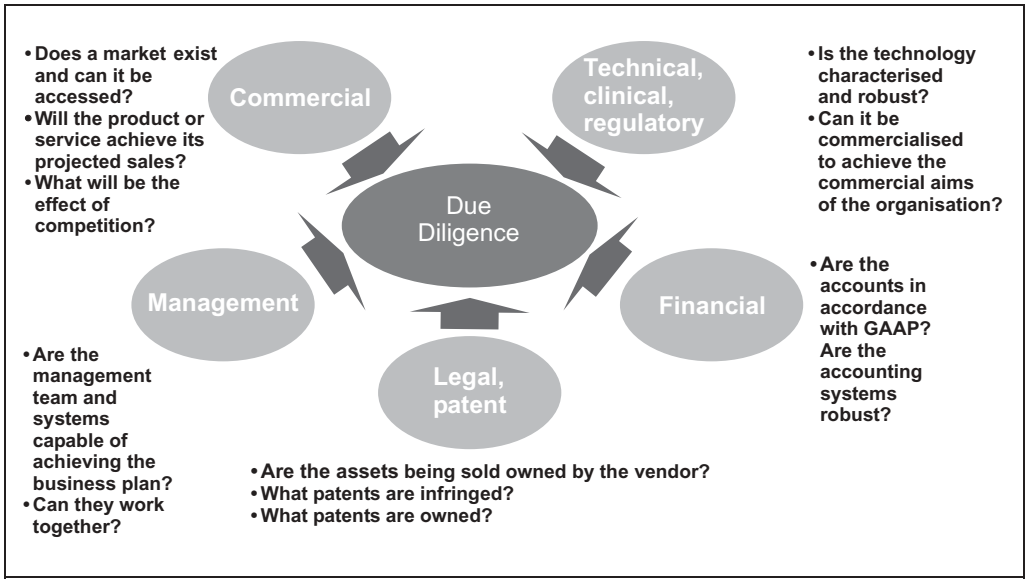


**Figure 1:** The key questions for potential collaborators are addressed by a thorough due diligence process (GAAP is Generally Accepted Accounting Procedures)

- human factors;
- fundamental technology.

**The due diligence term should be knowledgeable but independent**

In addition this due diligence team should be built up from individuals who are knowledgeable but independent of the area they are assessing. This independence can be critically important in shaping a collaboration that will be the most favourable for both partners and thus dramatically improves the chances of the collaboration being a success. The team should also possess the correct mix of fundamental business and technical knowledge, grounded in the real world of developing innovative products in the relevant industry sector.

**Due diligence should always be a two-way process**

Due diligence should never be a one-way process. If Company A is doing due diligence on Company B, then company B should be doing some due diligence on Company A. In many cases, the due diligence exercise has to be done in demanding timescales, and a robust process will be critical to deliver value from the exercise. This can usually only be achieved if the process has been honed and developed to deliver in the timescales required. A typical process is shown in Figure 2. The outputs at each step of the process should be used to define the direction of the organisation after the deal has been done.

## DEAL STRUCTURE

The collaboration has the potential to take many forms. These are outlined in Figure 3. In its broadest sense collaboration covers anything from licensing deals to joint ventures to mergers or acquisitions. When considering the deal type and structure it is important that the company should decide what its objectives are without letting managerial egos or subjectivity cloud the decision. Having decided on its objectives the company can begin to determine which deal structures are worthy of consideration and which will best add value. Of course it is unlikely that the options for any one situation will be as extensive as licensing to merger, but licensing might well be weighed against a joint venture. The due diligence process should allow both parties to understand how they can most effectively work together in the future. For example, PA Consulting Group recently conducted a due diligence exercise on a US biotechnology company with a view to acquisition by another organisation. The

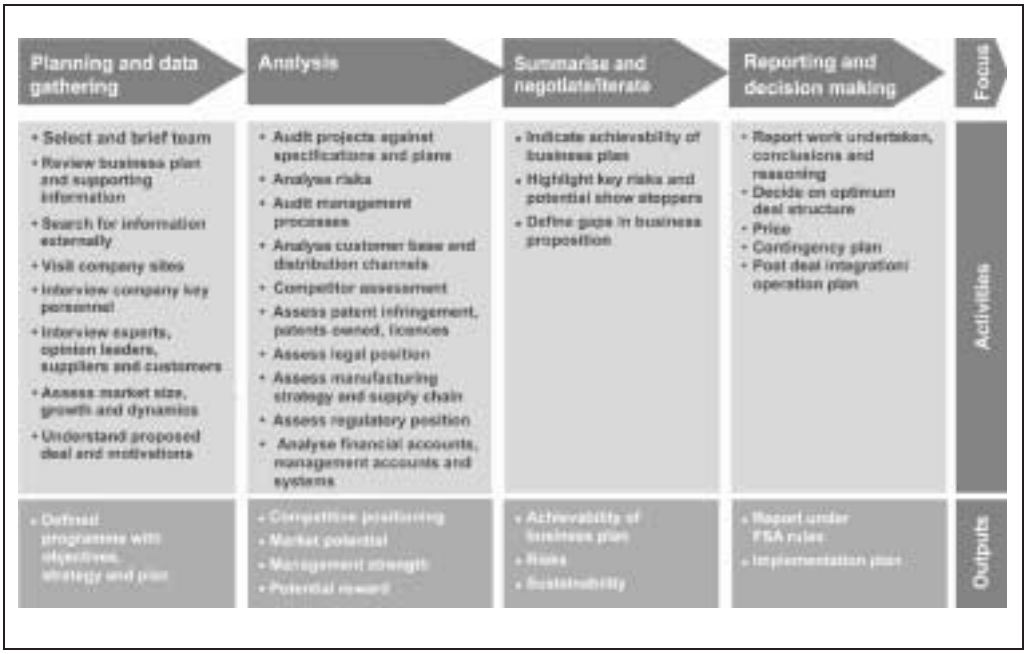


**Figure 2:** Framework for the due diligence process (FSA is the UK Financial Services Authority)

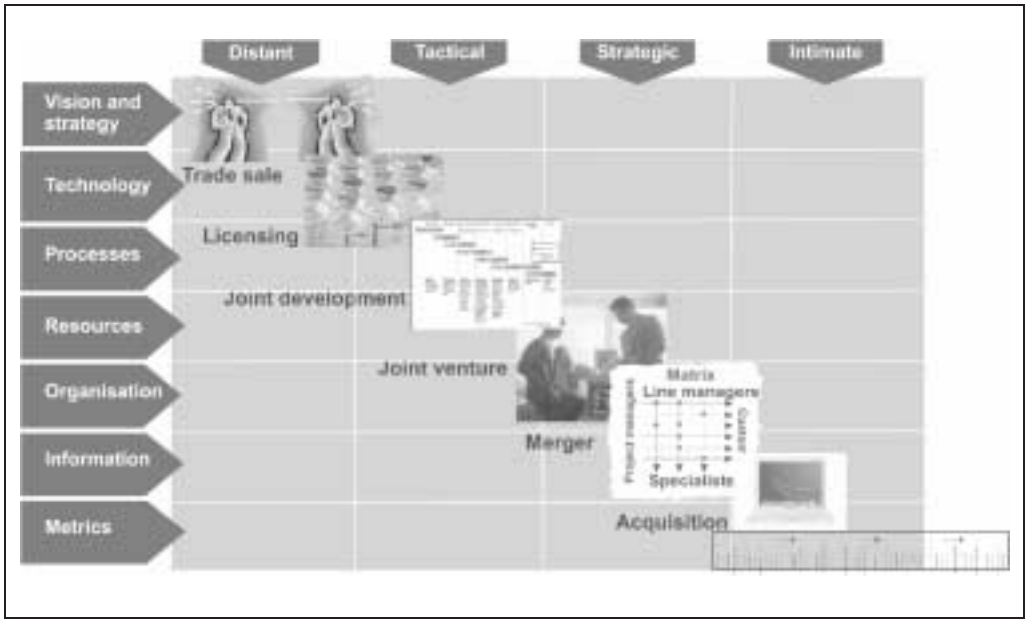


**Figure 3:** Types of possible deal structures between collaborators

due diligence process showed that in fact both parties would benefit more from one company funding a project within the other and taking a licence to their technology, rather than through an acquisition.

## POST-DEAL VALUE CREATION

**Value is created through execution of the implementation plan**

Above all else, the Implementation Plan must be executed; this is where and when any value will be created. The collaborators must adopt a learning and continuous improvement approach, exploiting the innovative culture that spawned the small company in the first place. The new organisation must generate a virtuous circle (Figure 4) of doing, reflecting, theorising and resolution to drive the organisation forward.

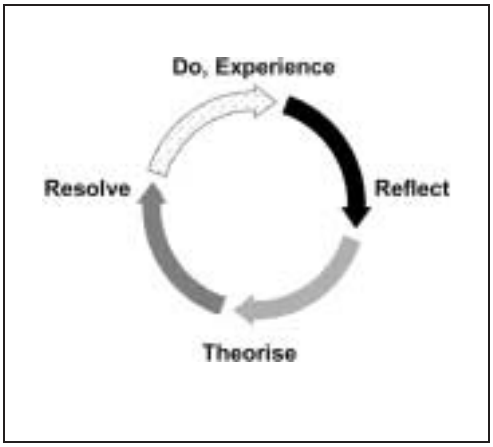


**Figure 4:** Virtuous circle that needs to be adopted by both partners to ensure a successful collaboration

## MEASURE PERFORMANCE

**The collaborating groups must measure success or failure through specific metrics**

A balance must be struck between the need for operational rules and formal structures, and the necessity for innovation and creativity. The collaboration must develop methods of measuring success or failure, through specific metrics that can be continuously monitored.

Metrics can normally be classified into one of three categories:

- financial measures;
- quality measures;
- time-based measures.

To be successful, the performance metrics need to define which attribute is being measured, why it is being measured and how it will be measured.

The metrics should also follow the widely used 'SMART' acronym:

- Specific – clear and unambiguous.

- Measurable – the factor must be quantifiable.
- Agreed – those being measured need to buy into the performance measure.
- Relevant – to the value-adding activities of the collaboration and realistically within the grasp of those expected to perform.
- Time based – with a clear timetable for the successful performance.

Clearly metrics will depend on the collaboration type. Those set for a merger or acquisition will be very different from those set for a licensing deal. It is also important that the metrics set are achievable for the individuals concerned. Typical metrics for the Board could therefore be about value creation within a given timescale, while those for project team members could be close to traditional personal performance metrics.

In our experience, too few organisations set metrics and even fewer are honest about evaluation against their metrics. Applied correctly, they can be used to monitor and manage performance so that corrective action can be taken where necessary in a timely manner.

**Too few organisations are rigorous about setting metrics and evaluating performance**

## SUMMARY

In summary, the drivers for collaboration between the biotechnology and pharmaceutical industries are stronger than ever. Companies should develop a clear strategy in order to steer and guide their collaboration activity – the due diligence process can be used to test the validity of this strategy. Rigorous and independent due diligence can provide the data and a basis for full integration planning with performance metrics – this is critical to increasing the effectiveness and value creation of a collaboration. Due diligence should be more than merely ticking a series of boxes at a late stage in the deal-making process; it can provide the ground-work for a successful and profitable relationship. Due diligence can be a powerful tool in progressively opening up a successful collaborative relationship as two organisations come together.



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