Evaluating Pharmaceutical Projects

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Evaluating Pharmaceutical Projects

Introduction

Pharma projects are inevitably subject to the compounding effects of uncertainty over time. This makes it more difficult to perform an effective appraisal of them, especially in financial terms. Paradoxically, the traditional approach of finance theory has been to pretend almost that such uncertainty does not exist. By focusing almost exclusively on the need to quantify value (and with precision) financial theory has turned the financial appraisal of pharma projects virtually into a ritual.

In the past, perhaps, strategic management has (with certain exceptions) gone into a retreat and allowed a financial perspective to become perhaps too dominant. In this chapter we seek much closer integration of strategic and financial appraisal for pharma projects.

Most major pharma projects require – sooner or later – a considerable amount of investment, whether this is capitalized on the company’s balance sheet or not. Often managers see doing the business case as a chore, especially when they have already gone past the point of ‘no return’ in their minds as to whether to do it or not. Where there is a lag between making the strategic commitment and the preparation of a business case, this may put a further psychological distance between the strategic thinking and the financial analysis. This implies, therefore, that both strategic and financial appraisal of projects needs to be fully integrated within a single decision-making process.

In evaluating any pharma project we must therefore take a closer look at the project appraisal process which might apply to a more complex pharmaceutical project, as follows (see Figure 5.1):

![Figure 5.1 Pharmaceutical Project Evaluation](image)
1. Project definition: Define the scope and focus of the pharmaceutical project, including its strategic objectives and context (as already seen in Chapter 3).

2. Definition options: Explore critical options for the decision and also any options which it forecloses (see Chapter 4).

3. Targeting and collection of data: Target data required having done a first-cut review of the kind of external and internal assumptions which will need to be made about key value drivers.

4. Assumptions evaluation: Collect and evaluate data through formulating the external and internal assumptions. Test these assumptions and re-visit the key options and work-up contingency plans.

5. Business case: Present the business case and, where feasible, refine the programme to add more value at less cost and at lowest risk.

6. Controls: Translate the business case into monitoring measures and controls.

**Understanding the business value system**

Before we examine this process stage-by-stage, we need to examine in more depth how value is created in business as part of a system which we can call the ‘business value system’.

The business value system can be defined as:

The set of interdependent situations within a business which either directly or indirectly adds value to the customer and ultimately generates a net cash inflow.

The business value system provides a context against which the value of pharma projects can be assessed.

The business value system is also more informative than simply talking about a ‘business model’, as it (a) focuses explicitly on value; (b) focuses on value creation as a system; and (c) specifically sets out to exploit interdependencies.

An example of a business value system is illustrated in Figure 5.2. This shows the impact of an IT project aimed at improving data capture. The key value creating activities represented in Figure 5.2 show:

- increased accuracy of data recording;
- ease of demonstrating regulatory compliance;
- possible, reduction in ongoing costs of administration;
- improved decision-taking (for example in achieving the milestones set by clinical projects in time
- provision of cost data for monitoring project costs.

Note here that increased accuracy of data recording feeds into the regulatory compliance process. Also, increased accuracy of data recording leads to some further reduction in costs via eliminating errors. Improved decision-making additionally further reduces costs. While this is a relatively simple business value system it nevertheless helps to show how a pictorial method
of visualizing the project’s context, and its interdependent value flows, is a healthy antecedent before ‘doing the numbers’.

By mapping out the business value system and showing where a project concept impacts both now and in the future, we can more easily understand how the project adds value.

We will return to the business value system during our later discussions of assumptions surrounding the declining base case.

**Stages in pharmaceutical project appraisal**

In this section we go through each one of the four main stages in the pharma project appraisal process (definition, options, targeting and collection of data, assumptions evaluation).

**PROJECT DEFINITION**

We have already explored project definition extensively within Chapter 3, ‘Defining Pharmaceutical Projects’, but now we need to turn to the linkages between this definition and financial appraisal.

First, if we examine the definition of the decision (or programme) more clearly we soon realize there are many problems in defining the unit of analysis. Is it a particular project or a more broadly-based programme? Where there are many and complex interdependencies it is frequently easier and better to evaluate the financials at the level of a set of projects (‘the pharmaceutical project set’ – see Figure 5.3). (Remember that we examined key project...
interdependencies in the section ‘Critical Path (and Uncertainty) Analysis’ at the end of
Chapter 4.) This requires analysis of the project in relation to other areas of the business. For
example, there may be a new drug being developed in a pharmaceutical company – the
equivalent of a Viagra for women. This might complement an existing drug for tackling male
impotency problems – particularly in terms of its marketing and brand synergies.

One of the biggest traps in evaluating project decisions is, therefore, to analyse projects at an
inappropriate level. Figure 5.3 suggests that you first need to question whether the project is
self-contained or not. Only if it is self-contained can you – at that point – determine that it
should be analysed as a distinct project.

Next, you need to ask whether there are many interdependencies, and, if so, are these simple
(thus enabling them to be analysed as a discrete project) or are they complex? If they are
complex then the final question is ‘is it easy to do a cost/benefit analysis of them?’ If it is not
easy, then you should not analyse this as a separate project. Instead, you should analyse it
among part of a higher level set of projects, or the ‘programme’ we described earlier.

**Exercise: Defining the level of evaluation for a major pharmaceutical project**

For one major pharmaceutical project you are involved in (or have been involved with
in the past year), ask yourself:
- Is the project relatively self-contained (or not)?
- Are their many interdependencies which impact on its value?
- Are these interdependencies simple or complex?
- Are these interdependencies feasible to quantify?
- Should we appraise the project at the level of the project set, or as an integral part
  of the business strategy?
DEFINITION OPTIONS

As we saw in the early part of Chapter 4, there are invariably many different options for defining any pharmaceutical project, all of which have major financial implications. For instance:

- Should the strategic objective be achieved through organic or through acquisitive activity?
- Is it more appropriate to move forward on the project very quickly or slowly?
- Is it worthwhile piloting its development prior to making a bigger commitment?
- Should commitment be delayed until there is a sufficiently strong implementation capability, enough resource, and perhaps better timing?
- Can the project’s key objectives be fulfilled at lower cost, or with greater flexibility through an alternative option?

And, finally:

- If we go ahead with this particular project, what other options (present and future) does this decision foreclose?

Referring to the start of Chapter 4, the project option grid is a useful way of scoping options and their potential attractiveness prior to getting involved in more detailed analysis.

TARGETING AND COLLECTION OF DATA

Once you have identified one or more options you should then identify the data required in order to assess the cash flow impact of any investment in the project.

Data can be collected from a variety of sources, particularly:

Externally

- From external distribution channels (for example, health authorities, hospitals, pharmacists, and so on) or patients by understanding whether any project or service meets the needs really important to them better than any competing drugs do.
- From any regulatory authorities, by understanding whether your drug is likely to meet the requirements of the regulatory authorities.
- From competitors, by finding out whether they are likely to be launching a competing drug in the near future.

Internally

- What is your operational capacity likely to be – and over time – from internal staff?
- What are levels of likely efficiency, operational flexibility and quality – again from internal staff?
- How high are unit cost levels – and how these will vary according to levels of activity – from financial spreadsheets and other estimations?
- What are the skills requirements in both quantity and cost – from human resources and operations?

At some point this data needs to be converted into cash flows, but this should wait until we have formulated the key assumptions which will underpin the pharmaceutical project.
ASSUMPTIONS EVALUATION

Defining the assumptions underpinning the value of the project requires considerable debate and challenge to provide a realistic basis for a business case. For example, if we go back to the new project in the earlier section on 'Project Definition' we might identify a number of key assumed cost value drivers. For instance, value drivers include:

- the new project adds superior customer value, being able to:
  - sustain volumes (of drug sales for existing customers);
  - increase margins (slightly);
- also, the project enables new customers (or distribution channels) to be penetrated.

Cost drivers include:

- the unit costs might be influenced by levels of activity through economies of scale;
- the cost of R&D processes, which is a key cost driver.

Here a 'value driver' can be defined as:

Anything either externally or internally within the business that might directly or indirectly generate positive cash inflows.

A 'cost driver' can be defined as:

Anything either externally or internally within the business that might directly or indirectly generate negative cash outflows.

Questions which help to test the external assumptions for a pharma project are as follows, in the categories of:

- the competitive environment;
- customers and market trends.

These questions give managers checklists for evaluating any kind of pharmaceutical project.

Questions on the competitive environment (for externally-facing pharmaceutical projects) include:

1. What assumptions about the competitive environment are implied by projected drug volumes, prices and margins, and how do these change over the life-cycle (for example, when the patent expires)?
2. How might specific competitors be either addressing the same opportunity already or might they be able to respond quickly to your move (especially with generic drugs)?

Questions on customers and market trends include:

1. How do customers (either distributors or patients) perceive the value of any end product or service upon which the opportunity depends? (Consider, the perceived value of the drug – in their lives, or as a big therapeutic issue, and so on.)
2. How important is this value creation within the customer’s own business value system (for example the patient, the GP, the healthcare authority) and what interdependencies is this contingent upon?
To test the internal assumptions underpinning a pharma project we now suggest that the following questions are asked. These deal with investment, costs and implementation assumptions.

**Investment-linked questions include:**

1. What capacity levels are assumed (in drug processing)?
2. What unforeseen areas of investment may be required either of a future or indirect nature (for example, expansion of office space) not currently included in ‘incremental’ cash flows?
3. What hurdle rate of return is appropriate for this kind of pharmaceutical project?

The cost of capital are more important where:

- cash inflows from investment decisions are relatively long term (particularly over five years hence);
- competitors might have access to cheaper sources of capital (for example, if they are based in Germany or Japan).

For pharma projects with shorter time horizons and paybacks, other issues – such as uncertainty, intangibles and interdependencies – will probably be much more important then calculating (and evaluating the value of) expected net cash flows over time.

**Cost questions include:**

1. How have ‘incremental costs’ been defined for the pharma project and how do cost apportionments incorporate a ‘fair’ allowance for direct and indirect resources absorbed by the activity?
2. What further R&D or other technical breakthroughs are assumed in order to support assumed levels of productivity?
3. What are the likely effects of reducing unit cost through gaining assumed economies of scale? Also, to what extent are unit costs increased if drug sales volumes are significantly less than ‘most likely’ assumptions?

**Implementation assumptions include:**

1. Are timescales for implementation of the project realistic?
2. Are there adequate operational resources to implement the project, especially where this relies upon scarce technical management and skills?
3. Is the area of drug development, or other area of advance, one where the pharma organization (and key individuals) has both the capability, the commitment and, where relevant, the appropriate culture to make it a success?

4. Who are the key stakeholders in the project, are they in favour, in neutral, or intangible, and what is their relative influence?

**Exercise: The internal evaluation of a major pharmaceutical project**

For the same pharmaceutical project (as you worked on earlier) that you are considering doing, ask yourself:

- What do the internal assumption checklists tell you about the durability of the project?
- What further data do you now need in order to formulate a robust business case?

Once the key assumptions have been defined, the next step is to begin to quantify the incremental cash flows associated with the project.

**Analysing Importance and Uncertainty**

While the above illustration is a well-worked-through example of financial appraisal, it is only as good as the assumptions on which it is based.

One way of now testing the external and internal assumptions for the project is by using the importance–uncertainty grid (derived from Mitroff and Linstone, 1993). Using this analysis grid (see Figure 5.4), managers can plot key assumptions driving the value of the pharma project decision. These can be external and internal, soft and hard assumptions.

![Uncertainty-Importance Grid](image_url)
An alternative format for this kind of analysis is the risk matrix, see Figure 5.5. Here, the likelihood of success is on the horizontal axis, and is graded in three categories: likely, possible and remote. Also, the vertical axis is the impact of success. This methodology is perhaps preferable where the project is not perhaps so likely to succeed. The uncertainty grid is perhaps superior when project success is likely, but you want to test its resilience.

Having selected a sub-set of these assumptions, these are now prioritized by using the grid. Once assumptions are carefully and skilfully defined, it is possible to debate the relative importance and uncertainty of these various assumptions, as we saw in Chapter 4.

At the beginning of the investment appraisal, key assumptions are likely to be mapped in the due north and north-east quadrants. Upon testing, it is quite common to find one or more assumptions moving over to the danger zone in the south-east.

Figure 5.6 now actually relates to the new product launch in the following illustration. The extra sales volume from existing customers is very important, but also considered relatively certain. Sales to new customers are considerably more uncertain (but also very important), as shown in the south-east of the grid (Figure 5.6). Product launch costs are somewhat less important and also reasonably certain (shown just slightly north-east of the centre of the grid).

In this illustration we refer to ‘payback’ which is defined as:

The period of time over which the initial project outlay is recouped.

In order to calculate the economic value of a pharma project, we need to examine its net cash flows; and to evaluate these using the company’s cost of capital.
This proceeds in a number of steps:

1. Ascertain or defining the company’s ‘cost of capital’ (based on input from Corporate Finance/Treasury).
3. Adjusting these to give a present (equivalent) value. This is done by discounting these future cash flows (that is, reducing their formula) to arrive at their ‘net present value’ (NPV) – the present value of future cash flows less the present value of all outlays.
4. Performing a sensitivity analysis of this NPV (following on from the uncertainty analysis conducted earlier).

The ‘cost of capital’ is usually the weighted coverage of the company’s cost of risk capital and the cost of its debt.

Outlays occur in the drug development stages (in drug discovery, pre-clinical, clinical trials and registration).

Net (positive) operating cash flows begin around year 13 and continue through to year 20 at (hopefully) a high level, to the end of the drug’s patent life and beyond. The bulk of outlays occur in phase III, during expensive clinical trials, when typically around 40 per cent of the cost of the drug research and development is incurred (through clinical trials).

Table 5.1 gives us a much simplified and fictitious illustration of a drug’s NPV. We have included (at year 20) a ‘terminal value’ of US$40m to cover the present value (at that stage) of the drugs net revenues, based on it now having become a generic drug. (An NPV is defined as being the present value of the cash inflows of the project, minus the present value of the outlays.)
The particular cash flow profile in the example gives an NPV of US$122m, which is a healthy return over-and-above the cost of capital. Given the risks inherent in the drug development and launch process this is not an unfairly generous level of returns. (For more on defining the cost of capital (which is beyond the scope of this book) see Grundy, 2002.)

For simplicity, in Table 5.1 we have shown the costs of developing not just one drug (in the early stages), but of many. For each successful drug a considerable number of compounds may need to be developed (to the clinical trials phase).

**Table 5.1**  An Example of a Financial Appraisal of a New Drug

<table>
<thead>
<tr>
<th>Years</th>
<th>R&amp;D Investment (US$m)</th>
<th>Operating Cash Flows (US$m)</th>
<th>Terminal Value (US$m)</th>
<th>Net Cash Flows (US$m)</th>
<th>Present Value** (US$m)</th>
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<td>40</td>
<td>2340</td>
<td>122</td>
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</tbody>
</table>

NPV is US$ 122 million or US$ 388 million less 266 million US$
* Sales less operating costs
** Assumed weighted average cost of capital of 12 per cent

As an alternative methodology, one might include in the computation only the drug development costs of a single compound. But we would then multiply future net cash flows from the drug by a probability factor, of, say, 5 or 10 per cent, to reflect the lack of certainty that it would be successful. A simple example of this would be (with a 5 per cent chance of ultimate success, and net revenues in year x of US$100 million):

Expected future value = $5\% \times US$100m
                            = US$5m

Clearly, to the extent that not all drugs will pass clinical tests and also might not clear
regulatory hurdles, then again an ‘expected value’ based on a probability × net cash flows should be used. The following points are interesting in Table 5.1:

- While the projects’ cash inflows appear to be considerable when each period is divided by a compounded annual factor of 1.12 (to reflect the weighted average cost of capital), the present value shrinks considerably.
- So too does the present value of outlays, to about half of the actual cash outlays: but the discounting effect of the cash flows in years 13 to 20 is that bit more harsh.
- The present value from generic drugs (following year 20) is very minor, (a) because of lower margins, but (b) because it is so far into the future.
- Should the project be delayed this may have a very big impact on NPV, (a) because you have less time before the patent expires, and (b) because cash inflows are pushed out into the future.

With regard to the final bullet-point above, it is possible (using the calculations above) to show how much a delay of a month, or even a day with cost in terms of NPV will cost. It is well known in the industry that these costs are large, and yet often project plans are unrealistic and get changed with an inevitably disruptive effect. These cash profiles are thus very closely parallel to Figure 5.7, sharing cash being recouped later on in the life of a drug.

![Figure 5.7: Net Cash Flow and Sales in the Pharmaceutical Industry](image)

**Understanding the Dynamics of Uncertainty – and of Scenarios**

Here the uncertainty-importance grid needs to be accompanied by some intensive thinking about the system which drives key uncertainties for any major pharma project. This can be represented as the uncertainty tunnel (see Figure 5.8). The uncertainty tunnel is depicted as a tunnel bounded by constraints on what is possible within a project’s environment. Essentially, uncertainty is seen as driven by unpredictable change.

In Figure 5.8 unpredictable change is explored by looking at its precursors (that is, what has affected the project previously from its environment). Pharma managers analyse these factors either amplifying or dampening a particular unpredictable change.
Following this analysis we can then examine the immediate versus the longer-term consequences of change on the project, perhaps discriminating between its first, second and third order consequences.

**Exercise: Using the uncertainty tunnel model**

For one project that you are contemplating, ask yourself:

- What are the precursors to the project?
- What factors might amplify uncertainty?
- What factors might dampen uncertainty?
- What are the potential first, second and third order consequences of a shift in the project’s internal or external environment? (Allow yourself to tell scenario stories at this point.)

Besides scenarios and more qualitative uncertainty analysis, a number of other methodologies have been used over the years to cope with evaluating uncertainty.

Forecasting the outcomes of drug development is a difficult process, and while estimates of drug’s economic value (or NPV) can be done on a spreadsheet, such single value assessments are unlikely to actually occur. Numerical methods known as ‘Monte Carlo’ methods can be used to look at the probabilities of possible outcomes on a computer. These are statistical
simulation methods that utilize sequences of random numbers to perform a simulation. The name ‘Monte Carlo’ was coined because of similarities with the game of chance in a casino.

When we use the word simulation, we refer to any analytical method meant to imitate a real-life system, especially when other analysis are too mathematically complex or too difficult to reproduce. A Monte Carlo simulation randomly generates values for certain variables and then uses a decision-tree methodology (see below) to simulate a model of expected results.

For each uncertain variable the range and frequency distribution is defined. The simulation calculates multiple scenarios of a model by repeating sampling values from probability distributions for the uncertain variables and using those values for the cell. Simulations can consist of as many trials (or scenarios) as you want – hundreds or even thousands – in just a few seconds. In drug development some of the key uncertain variables which can be simulated using Monte Carlo methods are:

- drug efficiency;
- costs of drug developing;
- time to market;
- penetration of market;
- drug price.

Monte Carlo methods are increasingly in use in the pharma industry as a way of coping with uncertainty and risk, and in making trade-offs between the various controllable variables.

Unfortunately, Monte Carlo methods are complicated and require sophisticated skills in interpreting distributions of possible results – they are not for the faint-hearted!

More specifically, decision trees can be used to explore the possible sequences of events which might occur within a project. Probabilities are then attached to each possibility. The ‘expected value’ (or the probability of the event multiplied by its pay-off) is then calculated. Decision-tree analysis is used quite frequently in the ‘go/no-go’ drug development decision-making process. This is done by working backwards using feasibility analysis, for example of:

- toxicity being highlighted from chemical structure (for example, oncogenicity);
- achieving the defined, unique, selling propositions;
- a commercially acceptable cost of goods;
- sufficient bioavailability for oral application;
- once daily application if required for marketing reasons; and
- a sufficient stable formulation.

Eventually one then arrives at a present, expected (economic) value for the project.

Figure 5.9 shows a decision tree for a pharma alliance. Alliances are particularly uncertain – due to a combination of market operational and political uncertainties. The decision-tree approach is thus particularly well suited to this area of application.

Figure 5.10 shows a typical decision tree for drug development and also one for business development generally. The advantage of a decision-tree approach based on pure expected
value is also simplicity. Its disadvantage is that it does not cope well where there is not a normal distribution curve of outcomes. So while one might have one expected value, the reality might be that in most situations the result would either be much better or worse.
Another way of looking at risks and uncertainty often used in the pharma industry is to look at how the probability of success changes as the various stages of drug development are completed (see Figure 5.11). This can also be used to help target improvements in project success rate through innovative methodology.

### Exploring the ‘do-nothing’ or base case

Before we leave the topic of assumptions for the pharma project we also need to explore the ‘do-nothing’ or base case option (Grundy, 1998a).

The base case is what might happen without the investment decision. Traditional financial theory teaches us to evaluate incremental cash flows, ‘incremental’ meaning the difference between net cash flows both with and without the investment project.

A major problem with the base case is that of predicting the rate or pace of decline. This is inherently difficult to predict. Some managers may then try to shield financially suspect projects behind the argument that unless the project is implemented, the strategic and financial health of the business will be irreparably damaged. See Figure 5.12 for a classic illustration of a declining base case.

The important thing to remember with the base case is that you need to spend almost as much time thinking about the world in which you do not do the investment as the world in which you do.
Returning briefly to the AID grid from Chapter 4, there are interesting implications of doing versus not doing the pharmaceutical project. Figure 5.12 shows the ‘with the project case’ as only marginally attractive, and also as relatively difficult. But with the ‘without the project case’, the business is actually in decline (and thus has negative attractiveness), and is very difficult. Thus although going ahead with the project does not look particularly wonderful on a ‘with the project case’ only, considering the negative base case that this avoids, it actually does become attractive. The value of this kind of project is thus protective rather than offensive.

These characterizations of value are just two of many possible examples of how to segment projects. For example, projects can have an ‘opportunity’ value in opening up doorways to future value. Or, they might have a ‘synergistic’ value along with other projects. They might also be of ‘sweat’ value, simply squeezing more out of the same or out of less resource. Finally, they may be of ‘deliberate’ or ‘emergent’ value, emergent value being value which was not actually anticipated, but which came out of unexpected alignment.

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**Exercise: Evaluating the base case for a pharmaceutical project**

For a project where, in a ‘do-nothing’ situation, the business revenues are in decline, ask yourself:

- What is the likely pace of decline?
- What might accelerate this pace of decline?
- What other measures (other than incremental investment) might mitigate the decline?
- Is the decline sufficiently cataclysmic to suggest that it may even be worthwhile exiting this business rather than investing more in it?

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**FIGURE 5.12 THE EFFECTS OF THE DECLINING BASE CASE**
Intangibles and interdependencies

With regard to intangibles, pharma projects add value only in so far as they are part of the business value system. Interdependencies thus need to be explored because they are essential in understanding how the business operates as a total competitive and financial system.

INTERDEPENDENCIES

Interdependencies exist in a variety of forms. Some interdependencies are external and reflect the impact of one external assumption on one another. For example, a resurgence of economic growth may increase the size of a particular market and also attract in new entrants.

Many of the internal assumptions depend upon external variables, giving rise to even more interdependencies (for instance, competitive rivalry may lead to a high incidence of price discounting and thus to lower margins).

But many of the more interesting interdependencies are those within the architecture of the business strategy itself. For instance, one product may benefit or suffer due to the introduction of a new product.

The analysis of interdependencies should follow on from the analysis and testing of the external and internal assumptions. Where the decision process is of a less formal nature analysing interdependencies should be integral with the evaluation of assumptions.

Exercise: Interdependencies of a pharmaceutical project

For one major project of your choice, ask yourself:

- What are the key interdependencies between this project and other projects within the business, or other business activities generally?
- What interdependencies are both most important and uncertain? (You may wish to use the uncertainty-importance grid at this point.)
- What would you need to do to align these interdependencies, and what might this cost?

INTANGIBLES

Intangibles are one of the main curses of project appraisal. For many managers, intangibles have become the ‘no-go’ zone of financial analysis. Although these areas of value are extremely difficult to quantify in financial terms (and perhaps impossible to quantify with precision), there are invariably ways of defining intangibles better. This can be done by looking at the project from different perspectives:

- Competitive: The impact on patient or other customer perceptions of value or in measurable improvement vis-à-vis competitors.
- Operational: Performance improvement or flexibility of operations.
- Organizational: The impact on morale and, indirectly, on motivation.
- Opportunity generation: The opportunity which might be opened up or explored as a result of the investment project.
The first step with intangibles is to ask ‘why is the value thought to be of an intangible nature?’ This may be because:

- The benefit accrues to the drug distributor or to the patient rather than directly to the company (either the patent or the channel to market). However, there may also be indirect benefits to the company via reducing the chances of the drug distributor switching to another competing therapeutic treatment or through increasing the price of the drug, or through protection against the discounting associated with the commodity, generic drugs. (This might take the form of a project to increase marketing spend on a generic drug whose patent has just expired.)
- The benefit accrues via a number of internal interdependencies with other areas of the business, or these may occur because the project is essentially part of the ‘business’ infrastructure.
- The benefit comes due to the project being essentially protective or defensive in nature.

A process for dealing with intangibles is therefore:

1. To identify why the value is of an intangible nature.
2. To seek possible alternative measures to help target and provide indicators of alternative measures to those of purely financial value (see Table 5.2).
3. Through management consensus, to compare what value managers are prepared to put on the intangible (this is sometimes called the ‘Delphi’ approach after the famous Greek oracle).

An example of managing intangibles can be drawn from ICI Biosciences (our case study in Chapter 1). A number of acquisitions of existing companies had been made, with ICI Biosciences paying significant sums for ‘goodwill’. These businesses were held at the time to have considerable intangible value, particularly:

- through providing the platform to exploit new breakthroughs in genetic technology (but what was the likelihood of this breakthrough, how would ICI capture its value in the marketplace using these companies, and for how long?);
- by achieving operational synergies with the other newly acquired companies (but who would harvest these synergies, how and when?)

In the event, these intangibles proved elusive for ICI Biosciences, the moral being: do not hide behind the difficulties of evaluating the intangibles.

**Exercise: Intangibles**

For one or more area of intangibles, in your pharma project, use Table 5.2 to examine the basis of their value and ask yourself:

- What is the underlying nature of this particular intangible?
- How might it be measured (or how might its key indicators be monitored)?
- Ultimately, if its full potential for cash generation is realized (both directly and indirectly), what might its value be worth?
We now develop a series of decision rules for managing intangibles. This takes us through the following stages:

- Why is the value intangible, for example:
  - Is it future and contingent?
  - Is it generated by value-sharing, for example, with customers?
  - Is it protective value?
  - Is it created by synergies within the pharma business value system?
- How is it created?
- When will it be created?
- How will it be captured?
- And by whom?
- How much value will be created, and at what cost?

**Business case**

We now examine what should be in a business case for a pharmaceutical project.
When someone says the words 'business case', managers often think of a weighty, detailed document with lots of hard facts and financial numbers. But the real point of a business case is to gain more clarity about the objectives of the pharma project, its implications for the business and particularly to expose and test the key assumptions which drive value. This can be achieved in a very succinct way, by, for instance, restricting the business case to a maximum of eight pages, as described below (often fewer pages are sufficient).

**SUGGESTED FORMAT FOR A BUSINESS CASE FOR A PHARMACEUTICAL PROJECT**

- Executive summary (1 page);
- project definition, objectives and scope (1 page);
- how the project adds value (new opportunity, tangible synergy, defensive or protective value – 1 page);
- key external and internal assumptions (with an evaluation of importance and uncertainty – 3 pages);
- implementation issues (1 page);
- summary financials (1 page).

This brings the length to eight pages, plus detailed appendices containing technical issues, market projecting distribution issues, technical details, detailed financial and non-financial measures and milestones, detailed financial sensitivities, and detailed resource requirements – possibly another seven pages. This brings a typical case to a total of just 15 pages, assuming that you write succinctly!

**Exercise: The pharmaceutical business case**

Using the above format for a business case for an existing pharmaceutical project proposal, ask yourself:

- What key questions remain to be answered about the value of the pharma project?
- What data do you now need to answer these questions (and at least calculate cost)?
- What process of management reflection, learning and review would now help to refine a most robust but realistic business case?

**CONSTRUCTING A BUSINESS CASE**

Below are some practical tips on putting together a robust business case for a pharma project:

- Involve a good spread of managers and technical advisers, and from a range of disciplines in project definition, option generation and data collection in a targeted way. This ensures your assumptions get a good reality check, and that you identify a wide range of options and also the key implementation constraints, and begin to position your project for endorsement.
- Be disciplined in your data collection: only collect data which will help you make the critical assumptions on which the project depends. (This actually means spending less time on those assumptions which are less critical, such as minor, internal overhead costs.)
- Integrate the data in a preliminary workshop to evaluate options and assumptions in a creative way. (Do not lose focus in a series of meetings spread over time.)
Take the point of view of other stakeholders in the organization. Consider which assumptions are most important to them and where will their judgements differ from yours, and why. Experiment here with the ‘out-of-body’ experience – imagine you actually are those stakeholders – what attracts you towards or repels you away from the project?

Do not try to obscure or conceal the project’s downsides. An astute review panel will quickly identify issues which you have glossed over. Your ‘out-of-body’ simulation equips you to have a balanced debate on the merits of the project.

Business cases will therefore only add value if:

- they are clear, succinct, and written in a jargon-free style;
- they expose the most important and uncertain assumptions, and also address these both in the sensitivity analysis and via contingency planning;
- they do not fall into the trap of seeing the financial numbers as absolute measures of value, but use these creatively – for instance, in dealing with less tangibles it may be fruitful to put an illustrative value on ‘what might these be worth?’ so that a more balanced, overall appraisal of the project can be achieved.

We have argued throughout the need to understand the key value drivers and to expose and challenge the key assumptions before undertaking the sensitivity analysis. ‘Better practice’ means doing very rigorous testing of those key variables which are likely to be most uncertain and most important.

It is only by working this way around that true sensitivity analysis is performed, otherwise all you may end up with is ‘insensitivity analysis’ – playing with the assumption-set to get an acceptable answer – a positive NPV (which in this case means no more than 'numbers prevent vision').

**Portfolio management**

‘Portfolio management’ can be defined as the systematic comparison of projects against two or more decision-making criteria. Portfolio management (see Figure 5.13) is the interface between R&D strategies and specific projects.

We have already considered a number of techniques for portfolio management. These include:

- the project option grid;
- the attractiveness-implementation difficulty grid (or ‘AID’ analysis);
- ‘economic attractiveness’ versus ‘feasibility’ – as criteria.

In addition, it may also be useful to rate projects against their likely return, versus risk. This can be done by using Figure 5.14.

The objectives of portfolio management are:

- to get highest and the best use of each project;
to allocate resources wisely;
- to select the right projects to achieve R&D and business objectives;
- to find a rational for prioritization;
- to gain commitment of organization.

Portfolio management is:
- needed in order to cope with multiple opportunities, limited resources, continual change and uncertainty – and differing time horizons;
is used to identify the gap(s) between the current portfolio and overall strategic goals, besides setting priorities and also resource allocation;
- is used to estimate both the economic value of the overall portfolio and of specific projects;
- can be used as a decision both to decide to rationalize a drug product portfolio.

Besides AID analysis (used for judging internal criteria), the criteria of ‘strategic attractiveness’ can be broken down into: product/market attractiveness, and competitive position (see Figure 5.15). In the pharma industry ‘product/market attractiveness’ would be broken down as follows:

- the attractiveness of the specific biology;
- the relative importance of the therapy in patient’s lives;
- the availability and relative efficacy of substitutes.

‘Competitive position’ can be broken down as follows:

- drug efficacy;
- mode lease of treatment;
- existence and severity of size of side-effects;
- likely market share;
- branding;
- ready availability of suitable distribution channels.

In conclusion, besides financial and probability analysis, portfolio analysis plays a very important role in evaluating pharma projects.
Conclusion

Project evaluation for pharma projects is not just a matter of number-crunching some cash flows in order to justify investment in the project. It is a very thorough testing, and in many cases a re-formulation of the project strategy – and perhaps even of its scope and main focus.

Project evaluation brings together analysis of both the external and internal pharmaceutical environment (and assumptions about that environment) – and translates this picture into value- and cost-driver analysis. Only when this is done is it feasible to begin a more detailed financial appraisal.