

New Product Development: Preliminary Assessment

The form collates information to inform decisions on selection and prioritisation for new product development

Additional documentation may be cited in your responses to individual questions.

Date prepared _____

Provisional Product Name _____

Prepared by _____

Group _____

Contact e-mail address: _____

Type of product:-

Minor upgrade

New to company

Major upgrade

Rival to competitor's product

General description of proposed product

Clarity about how this device (and its performance) will change the status quo

Q1: Please describe how this will change things (e.g. better patient outcomes, care delivery, other measures), comparing your proposal with existing procedures and/or devices.

Q2: Please describe the intended users and their roles (e.g. there may be an end user, a clinical user, and perhaps a carer who will help to operate it). What steps have you taken to understand each perspective, and what are your findings so far about of this device's impact?

Q3: How might this device compare in terms of cost and effectiveness with respect to current practice. While the best cases can be made through greater effectiveness and at lower cost, at this stage it may only be possible to indicate the factors that would contribute.

Q4: Please describe the preliminary specification parameters and indicate how these will affect the performance of the product in line with the clinical effectiveness stated above.

Regulation and re-imburement

Q5: How would you expect device or the service based upon it to be paid for, and on what basis would you expect the case to be made?

Q6: What regulatory class will the product be and will there be a need for clinical trials?

Capability

Q7: Describe the critical capabilities needed to design, produce, market and distribute this device. Identify any capabilities not available within the company, and make an initial suggestion as to how the gap may be filled.

Q8: How would you expect this to be manufactured (e.g. high volume, low cost; low volume, precision; contracted out)

Very basic business Case

Q9: Using your responses to questions 1-6 above, how many people a year are likely to use this product and how much is it likely to be worth to them. By estimating how much a payer would be prepared to pay for each device, or by a pathway assessment, produce a first-pass estimate of the potential annual market for this device

Q10: What is the anticipated development cost and timescale? How could this be funded?

Q11: On this basis, what sort of return-on-investment case could be made?

Q12: Who is your major competitor and how will this product affect your competitive advantage?

Q13: Please describe the top three risk factors and outline how they may be quantified within the next three months.

Notes:

These questions are designed to be used in a variety of scenarios:

- In a large company, this might be the first chance an inventor gets to record his or her idea for a new product. As such, this would form the basis of a case for a small amount of funding to take the idea forward and develop a proper business plan. Large companies would probably think of this as 'gate 0' in their business review cycle.
- In smaller companies, these questions may form the basis of an appeal for external, or even venture capital funding.

The aim of these questions is to bring together a number of factors that are critical to a product's success, and to encourage early discussion of them, even if the discussion cannot yet be complete or fully informed.

Q1. The main purpose of this question is to get inventors to consider the clinical impact of what they are proposing. A full QALY analysis will elude most at this stage, but some description is needed about the improvement in quality of life, extended period of mobility or independence, decreased pain or discomfort, or a more effective procedure (better alignment, fewer remedial procedures, etc). In terms of procedures, it is important that the inventor is able to articulate how this device will really improve the procedure.

In some senses, this is similar to a list of 'benefits' that might appear in a standard business plan – but it will contain a much stronger healthcare focus and will try to link the value to a set of users (see below).

Q2. An early focus on users is important because it forces the inventor to understand how the device might be used and in what context. This will clarify the sorts of methods that might be used to validate or inform the early understanding of the device. The second reason this is important is because it will be possible to provide a 'bottom-up' market estimate, if there are specific users in view.

It is worth trying to classify your users. MATCH has produced a preliminary classification of users into Types, Groups and Classes. For instance there may be an end user, a clinical user, and perhaps a carer who is also involved. Identifying each user is a critical first step (Shah et al, submitted on 5 March 09).

In terms of methods, the MATCH [User Guide](#) provides an introduction.

Q3. This question is designed to quantify the benefits outlined in Q1 above. Against this will be the cost – enabling a very crude, initial, cost-effectiveness analysis to be performed. A more detailed example of such analysis is provided through the MATCH spreadsheet tool. One benefit of attempting this analysis is that it may indicate that the product is under-priced.

Q4. Given the desired benefits and the user needs, it should be possible to identify and quantify the key elements of performance, or the important attributes, that would make a success of this device. Producing a draft, partial, specification at this stage will enable the device to be compared with competitive offerings in the market. It may be possible to write the specification in the box provided, or to append it as a single sheet.

Q5. If sales are envisaged on an over-the-counter basis, then a more standard product development business case may be appropriate. However, if there is an element of re-imburement (e.g. through NICE) then the inventor will need to consider how such a case is to be made, and to draw on the outputs of Q1-Q3 above. More complicated are cases where there may be mixed markets – e.g. it might be a self-pay 'top-up' to a funded scheme, or it might be that there is a 'medical' application (funded) and a 'public' healthcare application. It is critical that both routes to market are properly understood from the start, lest one channel undermine another. For instance, it

would be difficult to command a premium price for a 'medical' application, if the same device were on sale to the public as a healthcare application at a fraction of the cost.

Q6. This is straightforward. However, the classification will probably require the inventor to identify the appropriate regulatory framework, and perhaps company procedures that will apply.

Q7. This question provides an opportunity for an inventor to consider the wider implications of designing and bringing this product to market. A summary statement of which elements already lie within the company's capability would make a good start to this analysis. It may be, for instance, that a company has produced many devices in this field, but that this involves a new material, or perhaps a new type of patient.

When addressing this question, inventors should think as widely as possible in terms of capability: management skills (including ability to manage subcontractors), access to patient groups, testing laboratories, etc, are all important issues to consider.

Q8. While this question could have been a subset of Q7, there are now so many specialist manufacturers in the UK and overseas, that it is worth the inventor addressing this as a separate issue. Given the analysis completed in questions 1-6, it should be possible to estimate the quality and volume of manufacture needed, and to begin to consider whether it would be better done in-house or outsourced, and if so, to what type of company.

Q9. This question provides a stepwise method of estimating the market from the 'bottom-up.' This difference between this and many business development cases, is that we have already focused on the users, understand something of the impact on outcomes, and should be able to build a value proposition: this product is worth so much to each user because...

Given that the target price must always be less than the value to the customer (or why would anyone buy it?) and that the total cost of design, manufacture, distribution and after-sales must be less than the price (perhaps 50% of the price), you simply build up a picture of the market.

Q10. This question is aimed at providing a first-pass investment profile – what is it going to cost to develop this idea and how long will it take. The question of funding may be critical to the success of this idea, and so it is worth considering what external funds might be available and what measures would be needed to attract them. European and other funds are also available, but the timescales must match. For instance, there is little sense in apply for a large grant to cover a development programme that must be on the market in 4-8 months' time. If a collaborative project, or the involvement of a university partner is deemed beneficial, please state either what university, or what characteristics might best suit the need.

Q11. Each company will have its own method for doing this. A very crude measure can be made using a spreadsheet. Working in 6 month slots over, say 10 years, put in the costs and returns for each year and perform an IRR or NPV calculation (standard functions in Excel).

Q12. While a detailed analysis of the competitive position may come later – the inventor ought to find out who the major competitor would be. The fall-back position would be whoever is the main supplier in support of current practice. The response to this section should be related to the information furnished in addressing Q4 above.

Q13. Again, this forces the inventor to identify major risks and to suggest measures to quantify or discount them over a period of three months.

References:

Shah, S. G. S., AlShawi, S. and Robinson, I. (Submitted) 'Developing medical device technology from users' perspectives: A theoretical framework for involving users in the development process'. *International Journal of Technology Assessment in Health Care*. (submitted on 5 March 09)