Understanding the ‘big picture’

Black Swan Analysis works towards understanding the big picture when it comes to healthcare innovation.

The most exciting part of delivering some form of innovation in the healthcare arena is the empowering thought of it potentially changing, or certainly impacting, the current standard of care for patients and providing a step change in the thinking for a particular understood concept or theory, making it one step closer to an eventual solution. At that moment in time, the focus and enthusiasm tend to narrow quickly on the scientific novelty of what has been unearthed, and a belief begins to take control that this idea is unique and if it can be developed, the market will follow. To take it to this next logical step will require a level of financial funding to deliver the required data and evidence that will ensure utility in a commercial setting.

The financing journey

The start of any healthcare innovation looking to receive financial support, which could include various types of grants, will require, to varying degrees, a clear idea of what the innovation is intending to deliver to the ‘universal healthcare system’. This usually takes the form of a clinical unmet need that this technology is intending to address to a sufficient enough degree that would make it an option of choice and potentially a standard of care for clinicians. To the team in the lab, many of these embryonic concepts or ideas may feel a million miles away from ever being used in clinical practice, so understanding the contextual environment could feel too early to consider or maybe not relevant to what is being proposed, but this is exactly where the fundamental challenge lies for the innovator.

Regardless of whether the proposed innovation is healthcare related or not, the challenge for anyone trying to eventually commercialise an opportunity is firstly to ensure there is a significant enough demand, in terms of patients, that only your offering would be able to satisfy sufficiently. Initially, this could appear to be a moot point as a low likelihood of success combined with the many years required to develop the concept may make the realisation feel very distant. But it’s crucial for there to be enough addressable market at the beginning to make this a worthwhile opportunity to pursue. Using the right patient epidemiology data is critical in understanding this demand. In many cases, it may require identification of a specific sub-population of a larger prevalence or incidence disease population that would align with the innovative solution.

If you are unclear about the specifics of the patient population, you can easily overestimate eligibility. A good example would be in acute coronary syndrome (ACS), where there is data to suggest that approximately 350,000 males in the USA currently suffer from this syndrome. However, in the changing healthcare industry, this basic information is no longer adequate. Accurate, publicly available patient data could have limitations and be difficult to obtain if it’s for a rare condition or an orphan disease that will require the aggregation across several markets to get sensible population numbers.

It is now vital to further segment a patient population to better understand a disease area. In this case, of the male patients with ACS, 73% experienced a heart attack. By looking deeper into this sub-population, you can then see that 36% experienced a ST-elevated heart attack while 64% experienced a non-ST-elevated heart attack. This quickly demonstrates that the majority of male patients who experience a heart attack will be found within the non-ST-elevated heart attack sub-population. You may also need to refine the target population based on associated risk factors. In the case of ACS, the number of patients with a blood pressure over 140mmHg (high blood pressure) will need to be segmented.

Publicly available data sources can be used to help arrive at these numbers but should always be used with caution. A number of issues can affect the integrity of these sources; this can include caveats around methodology, representative sampling and data representation. Secondly, even with high quality data sources, they may not always provide the correct perspective or insight required for the data. A good example of this is GLOBOCAN cancer epidemiology data, which is extremely high level but does not provide insight as to staging or treatment rates. Other data sources, such as the Surveillance Epidemiology and End Results (SEER) programme from the USA, provide extensive coverage in terms of patients, attributes and outcomes but require a significant level of data interpretation and manipulation to be used in a meaningful or insightful manner.

Alternatively, the availability of robust databases such as Epiomic™ (www.epiomic.com) clearly shows not just the current volume but also future numbers for a specific patient population.
most suitable for investment, and can provide the building blocks to support a valuation or product forecast to receive funding.

**Market landscape**

As well as identifying the opportunity, the risks in the market need to be highlighted so the team has the capacity to put in place contingency plans, managing them to a degree that doesn’t jeopardise the eventual return on investment. This can take the form of a competitor, whether direct or indirect competition, adjacent technology and upstream changes to the treatment or diagnostic pathway. All of these factors can erode the potential, and in some cases, it could potentially lead to a form of creative destruction.

**The application of ‘longitudinal’ thinking**

One of the real challenges for innovators in the healthcare space is to have a perspective on what may happen in the future that might impact their product or offering. It may feel a bit like having a crystal ball, but this longitudinal perspective could allow you to modify or adapt your offering to ensure it continues to align with an unmet need. It’s important to have your eye on the trends in the current market as your opportunity may disappear over time and no longer be relevant. A good example of this ‘risk-awareness thinking’ would be the impact of the cervical cancer vaccine to address human papilloma virus (HPV). Unlike the majority of diseases, which have an incidence population continuously contributing to the overall prevalent population, an infectious disease, like HPV, will not just prevent the patient receiving the vaccine from getting HPV, it will limit the future spread that will lead to a reduced incidence population and shrink the overall prevalence patient pool. Unfortunately for an innovator who is developing a treatment or a diagnostic specific to cervical cancer, as these vaccines become successful, the original eligible patient population will shrink to a commercially unsustainable level for their novel offering.

**The application of ‘lateral’ thinking**

Along with having a long-game perspective on what the market may look like at the commercialisation stage of your product development, it’s equally important to ensure you have not missed a trick with where the optimal utility is for the product. There are numerous examples of where innovative technologies have started off being used in a completely different area before finding their way to their ultimate niche.

Thinking beyond the original constraints of the technology to apply it in areas where there may be untapped potential requires lateral thought processes to try and identify other unmet needs that could be fulfilled. The possibility of exploring markets and patient populations that may not have been immediately obvious or aligned with the original intention is a simple and effective way of extending a product’s commercial viability and success.

This could be as simple as applying the technology to other related disease populations which share similar characteristics as well as a common unmet need, for example a technology originally intended to monitor the presence of lung fibrosis in idiopathic pulmonary fibrosis but then finding utility in other fibrotic lung diseases.

In more complicated areas it may be a case of completely re-envisioning the use or application of the technology by distilling the original idea down to its fundamental components and reconstructing it in a different manner. Keeping with the example of fibrosis, if the targets are viable, then a technology which highlights fibrotic processes could be re-purposed to mark tumour margins as an aid in cancer surgery.

Since unmet need is centred on both the magnitude of the need and the scope in terms of the number of patients, this can be an effective way of contributing further to better health outcomes and commercial viability.

**Are you ahead of or behind the curve?**

Timing in the markets can play a key part in a technology’s eventual commercial success. Some of the most amazing technology invented will not be fully appreciated, because it is perceived as ‘ahead of its time’. In the case of healthcare, this could mean a diagnostic being available for a specific disease but with no follow on treatment available. Understanding the patient treatment journey and alignment with the current and future standard of care will eliminate any unwanted barriers to access or restrictions on use.

**The way forward**

Whether you are seeking funding from private investors or through the grant process like Horizon 2020, a strong understanding of the optimal utility for an innovative healthcare solution will require alignment with a current and future unmet need in the healthcare system. To give you the best chance for technical success in delivering your solution, and financial success with a compelling grant application, this will require a degree of longitudinal and lateral thinking to ensure you have maximised the potential and highlighted those hidden opportunities.

Having this clarity on what could impact you directly or indirectly within the market landscape could help you avoid a potentially painful realisation of the solution’s limited utility and the elimination of your team’s many years of hard work. Using robust data sources like the Epimic database can provide you with the precise information that will support this long term potential.

Not every market risk can be mitigated, but being aware of the potential challenges is the first step in addressing the potential problem and adapting the solution to ensure future success.