The ultimate test

Marc Kitten, senior partner and co-founder of Candesic, explains how the unique challenges of healthcare due diligence require both experience and expertise

Assessing a company's commercial attractiveness is seldom an easy task in any sector. It requires a detailed understanding of not just the business, but the market within which it sits. More than any other sector, however, healthcare presents unique challenges.

All due diligence requires an understanding and nuanced weighing of risk and opportunity – everything from the prevailing direction of the political wind, to the increasing use of potentially disruptive technology, to ever innovative ways to attract, train and retain good staff. But, with healthcare, that understanding is often far more technical and complicated, which also requires that investors get detailed layman explanations of the work done and its conclusions.

The healthcare ecosystem

Healthcare matters, as people's lives matter – few sectors can claim to have such dramatic relevance. The impact of healthcare extends well beyond patient care. The industry is a major employer; the NHS is the UK's largest employer and one of the largest employers globally by headcount, for example. The health of a nation influences its financial stability and preparedness for crises, such as pandemics, which can affect everything from economic productivity to national security.

Moreover, healthcare's breadth and multifaceted nature often requires understanding a broader set of sectoral angles – whether it is manufacturing for the production of equipment or technology for drug development.

Finally, the inherent complexities of healthcare are also driven by the long-term nature of the decisions taken; 10 years to develop and bring to market a new drug, for example. Also, the capital intensity of the sector, such as the investment required for a new hospital, and the angle of ever-evolving technology that impacts the entire value chain.

Medical expertise and scientific acumen

Healthcare consultancy is not a one-size-fits-all profession, and due diligence in niche areas often requires highly specialised knowledge. Frequently, healthcare consultancies are working in complex areas where there is limited market knowledge, and have to rely on personal expertise, the eclectic academic and professional background of their staff, and primary sourced data-driven research.

Depending on the brief, in healthcare services a background in medicine can be essential, as an in-depth understanding of clinical practices, protocols or medical terminology is needed.

The best healthcare consultancies have an expert to match any brief, often a doctor with relevant experience.

In pharma things get even more complicated. The ability to understand clinical trial data, the implications of various treatment modalities, and the effectiveness of healthcare delivery models may require extremely specialist knowledge.

Consultants with academic or scientific training are adept at interpreting complex data sets, understanding statistical methodologies and identifying potential biases or flaws in study designs. A nuanced understanding of clinical data ensures that consultants can differentiate between robust, evidence-based innovations and those that may be overstated or speculative.

Similarly, an academic or scientific background may be required for jobs where there is a need to understand the principles behind medical devices and the complexities of biotechnology. Sometimes, a combination of both is required.

Sometimes, what is needed is simply access. Candesic's commercial due diligence (CDD) of the leading provider of perfusion systems for life preservation, used in intensive care units globally, required the doctors of Candesic to access intensive treatment unit clinicians.

Technological advancements and innovation

The rapid pace of technological innovation in healthcare further complicates due diligence. Telemedicine, robotic surgery, personalised medicine and the ubiquitous artificial intelligence are just some of the advances transforming the sector.

Increasingly, even for a non-tech-focused company, scrutinising its technological capabilities, intellectual property rights, and the potential for obsolescence created by new technologies, requires not just a degree of specialised knowledge, but knowledge of technological trends, new technologies and their implications.

Candesic's recent CDD of a drug discovery company which uses big data and AI to investigate possible drug effectiveness required a detailed assessment of its technology – including a detailed understanding of natural language processing and machine learning – and of the strength of the clinical and AI development team.

High stakes and ethical considerations

All good consultancies operating in the healthcare sphere take a patient-centric view of their work and strive to improve care outcomes to drive better and longer lives. Healthcare directly impacts human lives, as mentioned.

The recommendations made during due diligence can affect patient care, access to services, or even impact overall public health. This adds an ethical dimension rarely seen outside of healthcare, placing an added level of responsibility on consultants. It also explains why a lot of pro bono work is done in this field.

This ethical dimension significantly influences the advice given. When working on the take-private of a leading UK provider of specialised social care and educational services for thousands of adults and children, Candesic was acutely aware this was an extraordinarily complex and sensitive area where consideration had to be given not just to CDD, but to quality of care.

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Regulation

No sector is as heavily regulated as healthcare – a reflection of the fact that mistakes can have life-or-death consequences. Regulations differ widely by sub-sector, by country, and sometimes even by region.

Germany's complex multi-payer healthcare system, for example, is decentralised and while overseen by the federal government, regulated at an individual state (Länder) level. In Spain, autonomous communities set healthcare policies, while Italy's 20 regions have substantially different health strategies.

At a sub-sector level, things become even more complicated. Take pharma, where a constantly evolving regulatory landscape balances innovation with safety, ethical and economic considerations.

R&D, clinical trials, and quality control are all rigorously policed, often by multiple agencies, each with their own unique requirements and processes. Patent law and exclusivity come into play here, as does post-market surveillance.

Healthcare regulations are not static; they evolve in response to scientific advancements and public health needs. Moreover, the healthcare sector is subject to frequent policy changes, which can drastically alter the regulatory environment. Consultancy firms must therefore stay continually updated to provide accurate and relevant advice.

Data sensitivity and security

As if all these complexities were not enough, healthcare data is also exceptionally sensitive and highly protected. GDPR, the EU ePrivacy Directive, and national health data regulations – such as the Federal Data Protection Act in Germany (which builds on GDPR) or Hébergeur de Données de Santé in France (security measures for organisations hosting health data) – provide a complex web of regulation and potential liability. A breach in this area can have severe legal and financial repercussions.

In conclusion, healthcare investment due diligence demands a unique blend of expertise, precision, and foresight. Investors must rely on due diligence teams that not only understand the intricacies of the business but can also navigate the complex regulatory environments, assess technological innovations, and recognise the ethical implications of their findings.

Healthcare investments often come with long timelines, significant capital requirements, and the potential for substantial impacts on patient care and public health. A thorough due diligence process ensures that the right risks are understood and mitigated, while opportunities are accurately identified.

However, given the stakes, successful healthcare investment due diligence requires more than technical knowledge. It requires a genuine passion for the sector, a commitment to understanding its nuances and a desire to positively impact the future of healthcare.