

Regulatory strategising in biomarker diagnostic companies: Perceptions, process and resources

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Pacific Channel Ltd and Caldera Health Ltd supported Lishia Singh, a student of the University of Auckland's Master's of Bioscience Enterprise programme. The support was in the form of a company internship that allowed the development of Ms Singh's commercial skills while she completed a project that had relevance for both Pacific Channel Ltd and Caldera Health Ltd businesses. Ms Singh undertook a research project title, "Regulatory strategising in biomarker diagnostic companies: Perceptions, process and resources." Her research was also supported with a Capability grant from the Ministry of Science and Innovation (formerly Foundation of Research Science and Technology).

The initial aim of the research was to provide recommendations to New Zealand biomarker diagnostic companies on how to best manage resource limitation, such as capital and human resources to allow the company to take their product through to the regulatory processes efficiently. The research uncovered the standardisation of such processes was very difficult due to the variability of context for each company and the nuances of decision making. To account for this variance in decision making the thesis document, completed in December 2010, explored the dynamics of decision making in regards to regulatory strategising for small biomarker diagnostic companies wanting to enter what they perceived as a major market. This was presented in the form of a conceptual framework.

Ms Singh's research identified three key insights that a New Zealand based biomarker diagnostic companies can use to navigate the decision making during the regulatory process. These key commercial insights suggest that a biomarker company should first develop in-house regulatory capability and then seek counsel from outside organisations to support these in-house systems, processes and capabilities. These insights are discussed in terms of three key processes:

Regulatory strategy

In order to capitalise on the understanding of local market dynamics it is recommended that companies' initial test market in their home base (e.g Australia and/or New Zealand) and subsequently enter a second market once regulatory approval had been gained in the initial market.

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The second market should be decided by two factors: knowledge of the market and the potential opportunity of the market. The more intimate the knowledge of a market the better equipped a company is to identify and engage in successful commercial activities in that region. Having experience in a regulatory process is useful and the closer the subsequent regulatory approval process is to the primary test market the greater the knowledge of the process.

The key exception when considering a second market entry is the United States. If wanting to commercialise a product in the United States the recommendation is that operations are moved to the United States. Given the expense of the FDA approval pathway companies with more limited capital may partner to resource this process.

Another recommendation that is made when formulating regulatory strategy in-house regulatory expertise should be harnessed as soon as possible. This is recommended as while consultants do provide useful services to the industry, the route to regulatory approval that they advise will usually be conventional and low risk approach more appropriate for established companies, which means in longer and more resource intensive pathways to regulatory approval. Consultants can be used to supplement knowledge for specific markets when needed. Furthermore, having a person in charge of the regulatory requirement of the company builds company capability and knowledge in-house.

Quality Management Systems

Quality Management Systems was commonly discussed as critical for the management of documentation and recording standards. The efficiency of these systems and the efficient implementation of these systems are important in ensuring the efficiency of regulatory processes. It is recommended that in-house regulatory expertise is acquired first. This ensures that the regulatory responsibility becomes a capability within the company. Consultants can advise on the system and provided templates but the system should be managed and implemented internally.

Clinical trails

The greatest risk when carrying out a clinical trial is investing large resources into a trial that provides incomplete or inappropriate data to meet regulators needs. To avoid wasted time and to ensure that limited resources are not sunk on insufficient trials it is recommended a professional statistician should be hired to guide the development of the clinical trials and interact with regulatory agencies. Contract Research Organisations were commonly used to running the trials however the in-house statistician should help guide the clinical trial design and communicate with

the regulatory agency.

These commercial insights as well as the conceptualisation of the decision process should help when decisions around regulatory strategy are formulated by early stage biomarker diagnostic based companies.

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