



MAKING A SUCCESS OF NEW DRUG DEVELOPMENT

Wasting \$60 billion on failed drug development programmes is unacceptable. But just how does the industry improve its strategy in getting new drugs to market quicker?

In 2009, the failure rate of new drug applications (NDAs) in the European centralized procedure peaked again at 40% — a trend that is showing no sign of declining.¹ The cost for the industry of failed drug development programmes is estimated to be \$60 billion worldwide.² These combined failures of pharmaceutical companies, of all sizes, to get new drugs to market is placing a huge toll on society.

Is it acceptable that a large number of patients are put at risk in trial programmes that have no chance of ever delivering a product to market? Is it acceptable that investigators and their sites are involved in studies of limited medical value? Is it acceptable that regulatory agencies are bogged down in assessing applications that cannot be approved? Finally, is \$60 billion spent every year on drugs that fail to get approved really sound business?

The industry needs to change this trend, to reduce the failure rate and to get new drugs to market quicker. In addition, there is a need to generate solid facts to encourage the termination of inferior drugs that are in development as early as possible.

Why do so Many NDAs Fail?

The European Medicines Agency (EMA) is transparent with the reasons drug applications fail and statistics are presented regularly that show why. The majority of failures are not because of poor molecules or therapies; they are the result of suboptimal clinical programmes and the resulting data that fails to demonstrate whether the treatment's benefits outweigh the risks to patients.

Usually, such deficiencies can be caught much earlier than is currently the case. Many of the programmes that have failed in late Phase III had sufficient signals to justify terminating the programme much earlier. Yet, because development was allowed to continue, patients were put at risk, agencies had to engage in activities that were predestined to result in refusals, and the companies in question spent huge amounts of money on trial programmes that would never succeed. In addition, the time spent on a failed programme could have been channeled into other scientific or business-related activities to create true value to the organization, patients and society as a whole.

Solving the Puzzle

To get to grips with these issues it is important to understand that any company will first and foremost look to its own survival. Indications that a company's single product is predestined to fail will not be appreciated by anyone with a vested interest. Expecting people within an organization

to step up and deliver this bad news at such early stages is perhaps not entirely realistic. This fact is also reflected in the statistics from EMA where external scientific advice was primarily requested by the bigger companies, who understand that engaging with regulators early in development will provide a roadmap to approval and are prepared to take the consequences in those cases when the news is bad.

Successful drug development is all about 'doing the right things right first time' and, to ensure this, drug developing companies should seek qualified third-party opinion before putting their plans into practice. Securing early third-party input and second opinion on the drug development programme is the only way to ensure that it is in line with external requirements and avoids internal bias.

According to research by the EMA, "obtaining and complying with scientific advice appears to be a predictor of outcome" (for a successful marketing authorization application) and "obtaining scientific advice early in development and at major transition points, as well as compliance with the advice given by the CHMP are recommended."³ Today, such impartial and qualified advice can be delivered through four main sources: FDA in the US; the EMA Scientific Advice Committee in Europe; the European National Competent Authorities; and through the NDA Advisory Board, an independent third party. The earlier this external advice is sought, the more value it will deliver to the development process, by providing intelligence on, for instance, clinical end point selection, trial design and regulatory strategy.

The most natural stages of drug development optimal for third party assessment are

- Non-clinical plan
- Phase I plan
- Phase II plan
- Phase III plan.

At each of these stages, external advice can provide practical, strategic, economic and societal benefits. It is of outmost importance to secure health economic and reimbursement requirements are covered no later than in the Phase III plan. This will ensure that the drug being developed is likely to be widely marketable once it obtains approval.

For the industry, as well as for society, the end goal has to be to get good medicines to patients faster. The pharmaceutical industry can, therefore, not afford to ignore the benefits of seeking external scientific and regulatory advice during their drug development programmes. Failing to do so risks them spending significant sums of money, resources and patients on studies that will not deliver regulatory success. **Pharma**

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