Planning for failure makes better business sense, as long as it cheap and quick

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Biotech companies involved in drug development should plan for failure, rather than success, says Dr Wilding, of Ian Wilding Associates.

Speaking to delegates at the White Rose Bioscience Forum in York today (31 October)
Dr Wilding, who has served as an expert scientist for the Food and Drug Administration (FDA), advises that many biotech companies fail to realise the range of clinical options available to them in the transition into human studies.

“Biotech companies need to think differently about drug development,” he says. “The FDA noted back in 2004 that only one in ten drugs that enter phase 1 clinical trials will make it to market, yet biotech companies plan for success every time. Facing such high odds of failure, they need to start planning for failure – and failure that is cheap and quick.”

For many years the phrase “failing quickly and cheaply” has been become a mantra within the industry but few companies have puts the words into action. However, the regulatory authorities now recognise that the “best model for man is man” and when moving into human trials, biotechs now have several key choices to make over the ‘how, why and when’. The FDA published its exploratory-IND guidance in January 2006, opening up regulatory approvals for different types of ‘first into man’ studies. There are pros and cons to each; however, Dr Wilding says that the new options allow companies to make cheaper and more rapid decisions on the likely success of drug candidates.

“The use of a conventional MTD (maximum tolerated dose) “first into man” study design for all development candidates for is now old fashioned thinking. Alternative concepts, such as microdosing or pharmacological effect studies using biomarkers, can provide early pointers as to the chance of success or failure for a new drug candidate. For example, enzyme changes might tell a biotech before expensive efficacy studies in patients that the drug is reaching the target site at the correct concentration. This approach is useful as it builds ‘yes or no’ signals and allows gradation of belief in that molecule or compound.

“Good science is good development and my advice to biotechs is to consider the old cliché “horses for courses”; investigate the clinical options, establish the programme risk profile, define the killer question and devise unique programs for each candidate. It will work out much cheaper in the long run,” he advises.

Source: White Rose University Consortium