

Genes are still incompletely understood and arbitrarily defined [10]. Genes as linear sequences of nucleotides could prove to be too simple a formula, especially for defining Intellectual Property. Interestingly, clashes between patent holders could be the cause of a revival of the scientific pursuit for the abstract rules defining the general properties of the gene in the post-genomic era [e.g. 2,13,14].

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## Decision-analytic approach: crucial to drug development ▼

In a recent article in *Drug Discovery Today* [1], Poland and Wada describe how pharmacoeconomic modelling can be used to guide drug development decisions. Pharmacoeconomics has become an important tool in guiding strategic pricing considerations and reimbursement planning [2]. However, as the authors show, pharmacoeconomic modelling can also be used to synthesize uncertainties and values to aid in the decision-making process during drug development. The authors decided to use the net present value approach to summarize benefits and costs. This is similar to the investment appraisal approach to clinical trial design suggested by Backhouse [3]. From the perspective of a pharmaceutical company, designing a clinical trial involves a series of investment appraisal decisions. Therefore, applying decision-analytic techniques to clinical trial design allows the explicit analysis of the assumptions and decisions to be made during the drug development process.

The case study by Poland and Wada is of particular interest because Highly Active Antiretroviral Therapy (HAART) has been shown to save costs to society in developed countries with a low unemployment rate, such as Switzerland [4,5]. This is because the human capital approach for estimating productivity costs is then typically used in a cost-effectiveness analysis from the societal perspective. From the healthcare

perspective, HAART has been shown to be cost-effective [4,5]. However, from the perspective of the pharmaceutical company, a cost-benefit analysis is required to assess whether the financial revenues outweigh the costs associated with the development of a new compound. The net present value approach does just that. The cost of discovering and developing a new drug has been estimated to exceed US\$300 million (1995 US\$) [3]. Given the high development costs, it is crucial to make decisions that maximize expected gains from a pharmaceutical company's perspective. A rigorous decision-analytic approach can help in achieving this goal.

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