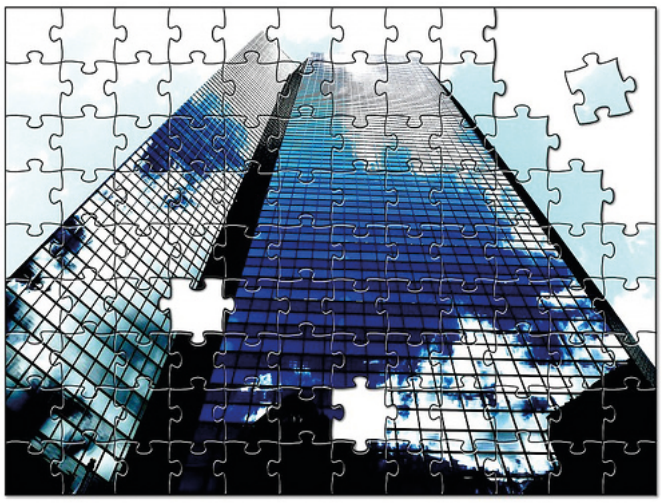
# Risk-sharing: Supplementing Clinical Trials for Payer and HTA Success

PEER REVIEWED

As the benefits of real-world data become more apparent so, too, do issues around its appropriate collection methodology and reliability. Olivier Ethgen, Scientific Director at SERFAN Innovation & EMIR (University of Liege), explores the creation of risk-sharing agreements and how to use this to mitigate against the potential weaknesses of clinical trial data.

**The Understated Requirement for Financial Analysis**

The optimum design of risk-sharing agreements requires the perfect understanding of the financial risks at stake. This point has unfortunately received very little attention so far - works published on the area are mainly descriptive, describing the different forms of agreements, but lack the required depth. Others have mainly insisted on the administrative burden resulting from this kind of contract. Too few studies have really tackled the challenging question of optimal design or focused on how to construct acceptable agreements from an operational viewpoint while providing financial guarantees to the two parties involved. We see this as an important area of research for the coming years in the field of market access.



To start exploring the creation of risk-sharing agreements, it is important to recall the two main forms of underlying financial risks that healthcare payers bear. In many European countries, the pricing of medicinal products is not free. The price and the reimbursement level of a new pharmaceutical product generally result from relatively exacting negotiations between the pharmaceutical company and the payer. In addition, the majority of payers attach a great deal of importance to health technology assessment (HTA).

**Combating the Inherent Weaknesses of Clinical Data**

During HTA and price negotiations, the decisions have primarily been based on the data generated by clinical investigation. This information is increasingly being considered as less than reliable by payers because its results, based on small patient cohorts, are not always transferable to the larger target population they are to be prescribed to. The manufacturers have the legal obligation to disclose all data and results stemming from their clinical research programme. However, this ex-ante information remains very incomplete. The risk-benefit ratio it carries remains quite unrepresentative of real-life conditions (the *ex-post* conditions).

Faced with such uncertainty, the launch of a new pharmaceutical product induces, among other things, an *ex-post* financial risk for the payer. This risk actually comprises two parts. First, there is the risk that the actual value of the drug will be lower than claimed, notably in terms of effectiveness. This is a risk of under-performance: the product does not produce the expected benefits within the target population. In this case, the risk is that the payer has to pay the negotiated price but for a product that proves to be less effective in daily practice as compared to the *ex-ante* performance documented by the clinical research programme and precisely used to set the negotiated price.

Second, there is a risk of over-prescription and/or over-consumption. The practical use of the product significantly exceeds the forecasts that were precisely used for the pricing negotiation. In this case, the payer incurs the risk of paying more than anticipated, putting at risk its budget planning ("volume" effect). This is also where the information between the pharmaceutical manufacturer and the payer is asymmetrical. The payer may have much less information about the market size, potential prescribing behaviours and uptake scenarios as compared to the manufacturer. Market research data are not necessarily disclosed to the payer.

The first type of risk leads to the so-called performance or outcome-based risk-sharing contracts. If a treatment is not up to its expectations, the manufacturer has to reimburse the cost of that treatment or to restore a fraction of the price, generally in the form of discount. The second type of risk leads to the so-called financial-based risk-sharing contracts. If the cost of a treatment exceeds the anticipated budget, the manufacturer has to reimburse a proportion of the difference between the planned budget and the observed budget.

The budgetary situation of many countries has perceptibly tensed up in the last number of years. Both forms of financial risk (i.e. paying for disappointing outcomes and paying more than planned) are becoming increasingly unbearable for payers. This risk aversion is


probably even further exacerbated as the cost of new pharmaceutical products continues to soar unabated. It is in this context that "risk-sharing" agreements between manufacturers and payers began to gain some momentum and attraction.

The major issue of risk-sharing contracts between manufacturers and payers is the understanding of the financial and operational implications of the contract. The collection and processing of the *ex-post* performance and volume of use of the product also deserve considerable attention. This information has also to be collected and managed impartially and transparently.

Modelling can help both parties to address these issues. In effect, a model can provide both the payer and the manufacturer with a series of assessments on the likely financial and operational implications of the contract they are settling. The ultimate objective is of course to design a contract whose terms are suitable to all stakeholders, including patients and clinical staff.

Modelling a risk-sharing contract can be broken down into two steps. First, the model should propose several prediction scenarios of the potential volume of use of the new treatment, i.e., the number of patients to be included over time in the risk-sharing contract. This is primarily a forecasting exercise. This step is quite similar to budget impact modelling already widely used in pricing and reimbursement negotiations. The time horizon should be neither too short nor too long and should fairly reflect the dynamics of adoption and diffusion of the new product. This time horizon must also enable the relevant real-life observation and evaluation of performance criteria for those agreements based on performance.

Once the dynamics of the target population to be included into the risk-sharing scheme is modelled, the model can estimate the financial implications for both parties. Indeed, in this second step, the objective would be to define the part that the manufacturer would have to return to the payer as per the contract terms and conditions. When contracts are based on the tracking of performance indicators, the extrapolation of the risk-benefit ratio into the real-life long-run can be taken from the cost-effectiveness analysis, which is now quasi-systematically carried out by manufacturers of new products. Note that during this step, the operational implications for clinical staff and administration can also be analysed across multiple scenarios.

By combining such projection assumptions, both parties are better able to anticipate the financial implications of the contract they may wish to conclude. In addition, such projections can also help to better understand the informational and operational requirements that will be imposed by the contract.

**In Conclusion**

In short, a risk-sharing contract is a form of warranty offered by a seller to a buyer. As such, it is a powerful selling approach and may help to secure the intended visible price of the seller. A risk-sharing strategy has unquestionable financial implications for the manufacturer. It is recommended that risk-sharing is a full part of the market access strategy of costly products. Multiple approaches and scenarios should be thoroughly thought about early in the process and modelling can help in this matter, borrowing analytical tools from the field of finance. Results and analytical frameworks of budget impact and cost-effectiveness models can also be used. As demonstrated, risk-sharing agreements should be considered and implemented as part of a controlled strategy; the last thing for a seller to do is to offer a warranty based on unexpected negative outcomes from negotiations.

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