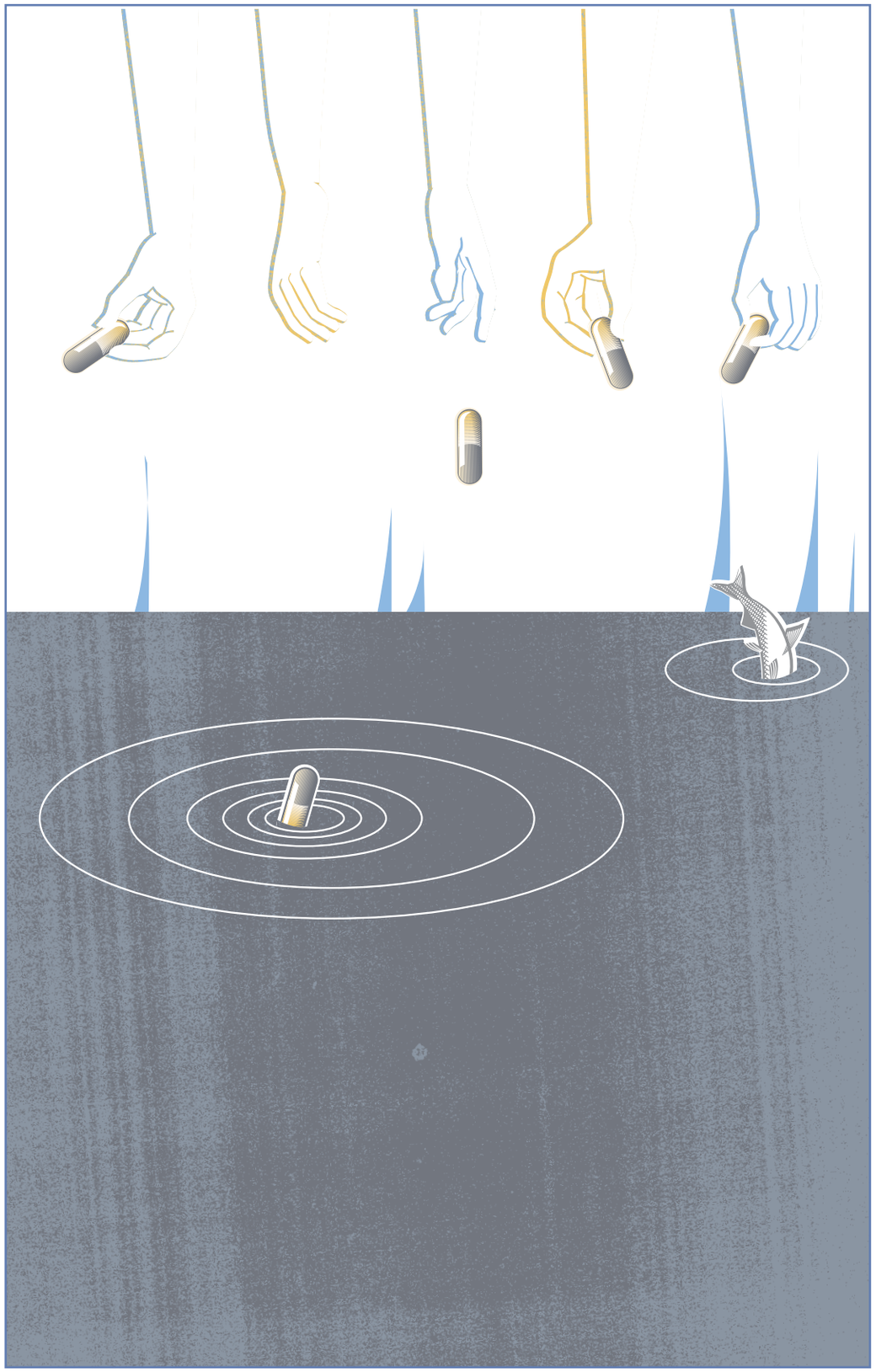


# Making new product launch decisions in an uncertain environment

*Vincent Wille, Pieter-Jan Mermans and Edouard Croufer*

**Product launch is becoming ever trickier, as the environment into which the new product will be launched changes constantly. This is particularly true for the pharma industry. The launch of a new product presents developers with a whole variety of risks - technical, commercial, competitive and regulatory. In this article, using the launch of a new medicine as a case example, the authors examine the problem and offer a pragmatic and effective solution.**

What do, say, a new Fiat car, a Sony game console, a Coca-Cola soft drink and a Pfizer medicine have in common? Well, if the manufacturer messes up the launch of the new product, its bottom line and balance sheet – as well as some careers – will get hit very badly for years to come. Indeed, in any industry with long development lead-times, one cannot afford to make the wrong decisions when preparing the launch of a major new product: which product variants to launch, in which countries, at what time, in which sequence, and at what price?

If we lived in a static world without uncertainty and complexity, these decisions would be fairly easy to make. Early in the new product development process, one would define a couple of alternative scenarios, calculate the corresponding cash flows, pick the scenario with the highest net present value, and get going. Unfortunately, the world is pregnant with unknown facts and future events, the arrival of which is controlled only to a limited extent – or not at all – by the company developing the new product.

Take the following situation in the pharmaceutical industry, for example. Assume a pharmaceutical company has identified a new molecule that treats multiple diseases. Specific clinical studies will have to be performed for each disease. Likewise, the product launch approach – addressing matters such as regulatory approval and price negotiations – will have to be differentiated by disease. One important decision relates to the sequence in which the medicine (in its various forms, such as tablet and capsule) is introduced for the multiple diseases, as the price and reimbursement conditions that are obtained for the first disease will dictate the conditions for the subsequent disease(s).

Imagine, for example, a product that can be used for both a life-threatening oncology disease and a non-life-threatening gastro-intestinal disease. And assume that the clinical studies are completed for the gastro-intestinal disease

first and the green light is received from the authorities. The company could decide to launch the new potential blockbuster immediately in order to start recouping its R&D investment as the patent expiry clock is ticking. In doing so, however, the chances are that the extra revenues generated by this early launch will be much smaller than the total revenues generated by launching the medicines for both diseases at a later stage at the higher prices dictated by the oncology disease.

The above example illustrates that new product launch decisions can be both critical and complex. Generally, the uncertainties are of a varied nature:

- Technical: Will the product work? For example, for a new medicine, will the clinical trials confirm its safety and efficacy?
- Commercial: Will customers buy the product? For example, will doctors prescribe the new product to as many patients for as many days as planned?
- Competitive: Will competitors be better? For example, will another pharma manufacturer be early on the market and set the price benchmark?
- Regulatory: Will the regulators shift the goalposts? For example, will the Food & Drug Administration modify its reimbursement policy for the treatment?

*Executives want to postpone complex decisions as long as possible, so that they can take the latest facts and events into account, and increase the chances of a successful launch.*

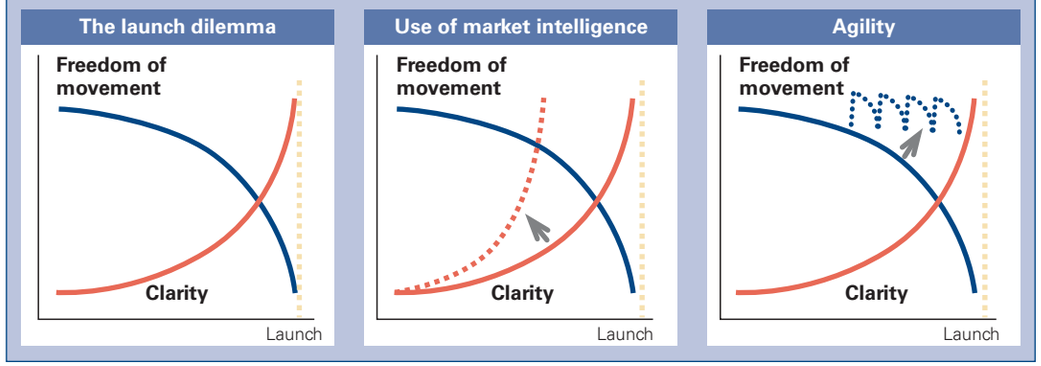
Obviously, the answers to these questions can be ascertained only when it is too late, that is after product launch, when all product launch decisions have already been made. Therefore, executives want to postpone these complex decisions as long as possible, so that they can take the latest facts and events into account, and increase the chances of a successful launch. But there is the dilemma: to be able to move the development of the product forward and shorten the time-to-profit, decisions must be taken as early as possible. In other words, how can management push back potentially fatal decisions as long as possible without jeopardising the launch time?





Faced with this launch dilemma, some people will answer that it is a matter of hard-nosed quantitative analysis. They argue that proper market intelligence and management skills make the difference. Others will answer that it is a matter of gut feel and agility. They argue that the power of forecasting is illusive, and that the ability to respond quickly to changes makes the difference.

Exhibit 1 **How to address the launch dilemma**




We believe that both quantitative analysis and agility are necessary requisites, yet insufficient to make the difference between launch success and failure. Through our work for a variety of companies, we have developed an approach to solve the launch dilemma in a pragmatic and effective way. Although our approach can be used in any situation, for relatively easy launch situations (those with a high degree of internal freedom, little uncertainty on product quality, no regulatory constraints, etc.) it will come close to traditional methods such as scenario modelling. Our approach adds true value in more complex situations where other methods fail to grasp the sheer number of variables, the spill-over effects between those variables and the uncertainty factors influencing the final result.

While explaining the principles of this approach in this article, we will use the launch of a new medicine as an illustration, as this is probably one of the most complex launch situations an industry might face, involving uncertainty on product quality, high competition and national regulatory constraints, to name but a few influencing factors. While this illustration is based on a real case, for reasons of confidentiality we cannot reveal detailed information.

Central to our approach is the combination of a "hard" and "soft" side. The two are equally important:

- A comprehensive and user-friendly quantitative model that allows calculation and easy comparison of the net present value (NPV) of different launch options, not only in one but in all possible future states of the world.

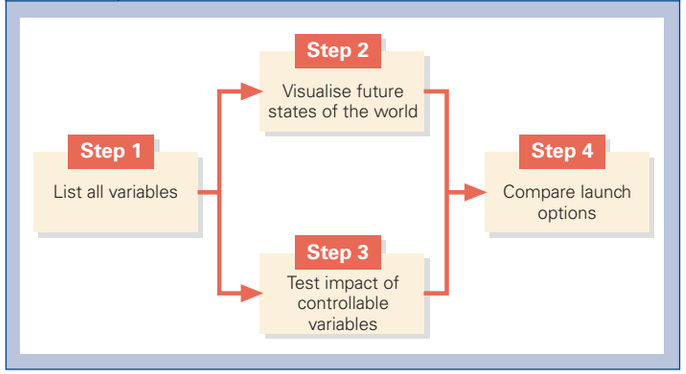
- A dynamic group process, bringing around the table all disciplines concerned in the launch of the new product, compelling them to develop a shared understanding of what influences the launch and how the marketplace could evolve.

*Companies looking for a plug-and-play calculation model from which hopefully to get the magical solution at the push of a button often ignore the value of the "soft" side.*

Companies looking for a plug-and-play calculation model from which hopefully to get the magical solution at the push of a button often ignore the value of this second side. It is extremely important to feed the model with the most correct and complete set of data available in the company, and this needs experts from all affected disciplines. In a pharma company, for example, the disciplines to be involved range from sales and marketing, regulatory affairs, clinical development and product quality to pharmaco-economics.

The approach consists of the following steps (Exhibit 2):
1. Unravel the plethora of variables influencing the launch options;
2. Visualise all potential future states of the world;

Exhibit 2 **Approaching the launch in 4 steps**








3. Test the impact of the variables under control of the company's management;
4. Compare the launch options, taking into account both the expected NPV and risk profile of each.

**Step 1: Unravel the plethora of variables influencing the launch options**

To build a proper understanding of complex new product launch decisions, you need to bring all disciplines concerned around the table. Each of them should contribute to the making of an exhaustive list of key variables that will impact the creation of value through the new product. Still too often, managers have an intra-disciplinary view on how to launch new products. A cross-departmental approach allows the building of a holistic view on why and how certain variables impact value creation.

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After prioritising the variables in terms of their impact on value creation, determine which of them can be steered directly by the company's management (controllable variables) and which cannot (non-controllable variables). Typical variables include country launch sequence, marketing effort, product price level and competitive reaction.

Let's apply this to our example. As we have seen before, one and the same molecule often serves to treat multiple diseases in different therapeutic areas. The optimisation of a product launch includes the optimisation of the sequence in which the medicine will be launched in the various countries and for the various diseases. For that reason, the list of controllable variables must definitely include country sequence and disease sequence. Other controllable variables impacting value are the initial price level, sales effort, marketing spend and the scope of additional clinical trials.

Non-controllable variables may include general macro-economic factors impacting value creation (such as a country's GDP), the level of competition and, more specifically for the pharmaceutical industry, regulations, because each country's government adopts its own regulatory policy when it comes to medicine approval and reimbursement. Hence, non-controllable variables originating from the reg-

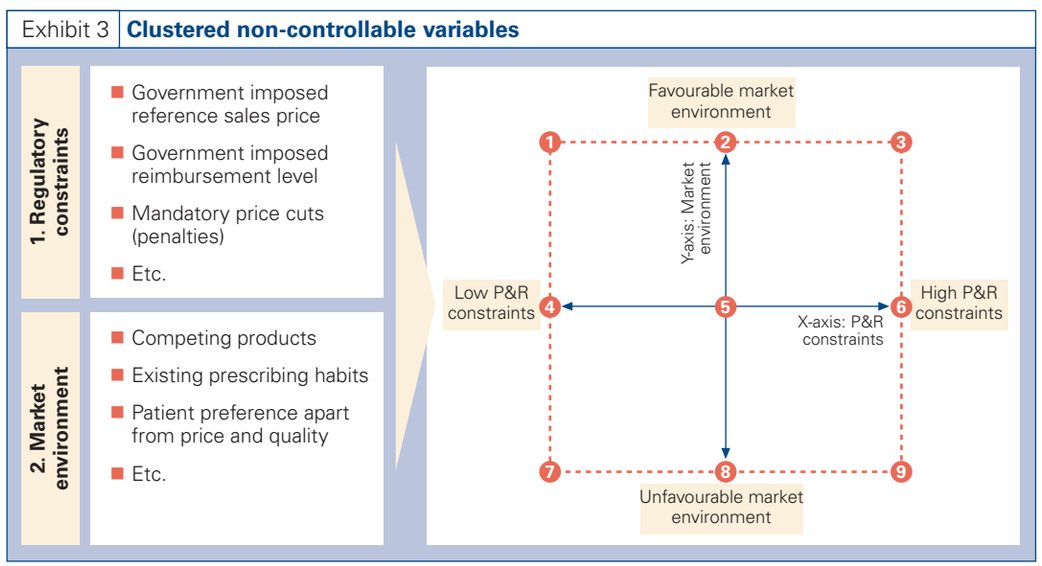
ulatory area include elements such as government-imposed reference prices and reimbursement levels, specific reimbursement, therapeutic and prescription guidelines, and government incentives for the prescription of generics.

**Step 2: Visualise all potential future states of the world**

With regard to non-controllable variables, describing multiple, probability-weighted states of the world is essential to provide an analytical and robust understanding of where value might be created. To that purpose, cluster the non-controllable variables into independent dimensions. Potential future states of the world are described by different positions in this multi-dimensional space. The definition of the dimensions depends on the industry and the geography for which the model is constructed.

For our example in the pharma industry, we found that a two-dimensional space, formed by a 'market environment' axis and a 'regulatory constraints' axis, is particularly useful in describing realistic states of the world (Exhibit 3). Non-controllable variables such as reference price, reimbursement guidelines and mandatory government price cuts are typically clustered on the 'regulatory constraints' axis, while competitive initiatives, prescription habits and patient preferences are clustered around the 'market environment' axis.

Exhibit 3 **Clustered non-controllable variables**







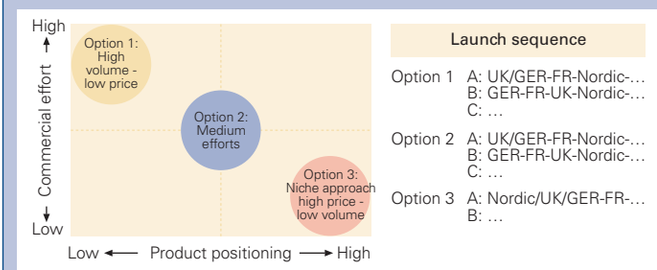

By describing the nine indicated points in this two-dimensional space, in which a correct assessment of the extremes is key, management can visualise the total space of potential states of the world in which the medicine will be launched.

**Step 3: Test the impact of the variables under control of the company's management**

In parallel with step 2, a detailed investigation process should be launched to understand how cash flow items such as revenue, operational expenditures, working capital and capital spending should be linked to the variables in the model. The objective is to be able to translate changes in the values of the variables automatically into changes in the cash flow items. For the controllable variables specifically, this implies that a significant part of the investigation should go into understanding the elasticity of the variables. For example, sales effort and marketing spend are two typical controllable variables on which to gather data about the incremental return from incremental sales or marketing effort. Although managers spend significant marketing budgets on a regular basis, statistical analysis of how these investments really impact sales is often lacking in quite a few industries. If that is the case, identify and prioritise the needs for further investigation, as the elasticity of variables is a key data requirement for understanding how to optimise product launch decisions.

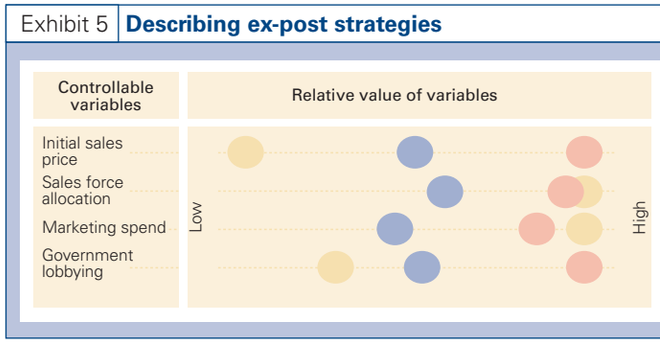
Furthermore, to hone the thinking process, draft a number of ex-ante launch strategies before using the model (Exhibit 4). These are launch options that a priori appear attractive. For the pharma industry, for example, we would define ex-ante launch strategies along three clusters of controllable variables: product positioning, commercial effort and launch sequence.

Exhibit 4 **Drafting ex-ante strategies**




The ex-post launch strategies are described through the individual controllable variables that can be fed into the model. The final impact on company value is subsequently calculated based on the elasticity as described above.

Exhibit 5 **Describing ex-post strategies**




**Step 4: Compare the launch options, taking into account both the expected NPV and risk profile of each**

Finally, test various launch strategies, i.e. multiple combinations of settings of the controllable variables, in order to build an understanding of how most value is created. Use the model to test each launch strategy for each of the potential future states of the world, in order to verify the robustness of the launch strategy. If a launch strategy shows positive results overall, but (very) negative results under one or some of the states of the world, one has a strategy that could lead to high returns but also contains high risks, i.e. it is not robust.

In the pharmaceutical industry our experience is that this approach can result in choosing counterintuitive launch strategies. Price differentiation for the same molecule that serves to treat multiple diseases often results in significant financial benefits. Spill-overs in terms of reference pricing across countries are often substantial. Consequently, and contrary to common sense, postponing the launch of a new molecule in certain countries could generate incremental financial benefits. Strong acceleration versus explicit postponing of the launch of other diseases treated with the same molecule could yield significant value.

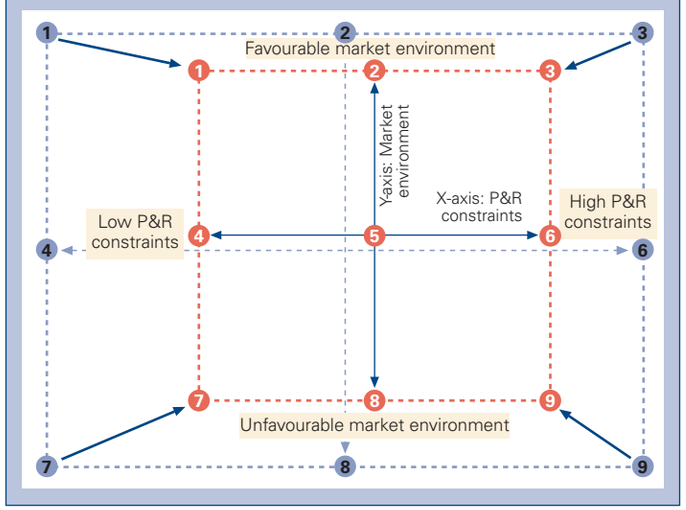
*The success of this approach lies in the involvement of all relevant disciplines. Running through this four-step process once with all disciplines will yield an understanding of the potential states of the world and the possible returns of selected launch strategies in those states of the world.*

As mentioned at the beginning, the success of this approach lies in the involvement of all relevant disciplines. Running through this four-step process once with all disciplines will yield an understanding of the potential states of the world and the possible returns of selected launch strategies in those states of the world. Ideally, this should be a recurring process up until the very moment of the launch itself. Over time, the degree of uncertainty with regard to the potential states of the world diminishes, as changes to the regulatory environment become less likely, while the behaviour of the market becomes more transparent.

In other words, some extreme values in the initially defined space of "potential states of the world" may turn out to be unlikely. A new, smaller space of "potential states of the world" should therefore be defined, in which the new space will shift toward one of the quadrants of the initially defined space (Exhibit 6).

By repeating this exercise over time, the accuracy of the outputs will grow, even more so as the model is capable of revealing the relative importance of all variables. This in turn allows the company to prioritise its market research by focusing on those variables that have the biggest impact, providing a competitive edge to the user in terms of truly relevant market intelligence.

Exhibit 6 **Narrowing the space with "states of the world"**




## Insights for the executive

Decisions about the launch of a new product are fraught with difficulty. The market environment is uncertain and partly uncontrollable, and transparency in value drivers is lacking. Making the wrong decision about which variants to launch, in which countries, at what time, in which sequence and at what price can have severe financial consequences. Our approach drastically improves the complex decision-making process by enhancing transparency and pinpointing specific risks. Central to this approach is the combination of a quantitative model and a dynamic multi-disciplinary group process. By confronting alternative launch options – as defined by variables under the control of the company's management – with potential future states of the world – as defined by variables that are not under the control of the company's management – executives can make product launch decisions that maximise value creation.

*Vincent Wille*
*… is a Manager in Arthur D. Little's Brussels office and member of the Health Care Practice. He specialises in strategy development and organisational work including post-merger integrations.*
*E-mail: wille.vincent@adlittle.com*

*Pieter-Jan Mermans*
*… is Consultant in Arthur D. Little's Brussels office and member of the Strategy & Organisation Practice. He specialises in BU strategy, strategic project evaluation and pricing diagnosis.*
*E-mail: mermans.pieter-jan@adlittle.com*

*Edouard Croufer*
*… is a Director in Arthur D. Little's Brussels office and heads the worldwide Chemicals Practice. Before joining Arthur D. Little he was a senior executive at Exxon Mobil Chemicals and UCB.*
*E-mail: croufer.edouard@adlittle.com*