June 2000, Tony Blair and Bill Clinton held a joint press conference at which they announced the completion of the Human Genome Project— the availability of a first draft of the genome or genetic code of the human being. This milestone, one of the greatest scientific achievements in human history, means that today our generation may well be facing a quiet revolution which will change our current understanding of medicine, ushering in what is generally known among the scientific community as personalized medicine.

This new situation will allow the progressive application of treatments—preventative and curative—based primarily on individuals' genetic information. This contrasts with the situation to date where it has been based on symptoms, in a system where the doctor's opinion and experience were of vital importance. The promise that personalized medicine holds out is for an improvement in the effectiveness of treatments and a reduction in side effects, since they will, a priori, be targeted at those individuals, and will have a better response.

For the time being, in a ten-year timescale (the period for which the forecasts in this study are based), we will not see individualised treatments for each person, but mainly segmented treatments, targeted at groups of individuals with similar genetic features. This marks, nonetheless, a substantial change over the prevailing concept at present of "one-size-fits-all" treatments and drugs, under which all research has centred on finding pharmaceuticals for a wide majority of the population suffering from specific ailments.

These changes have been made possible by the enormous advances achieved in both molecular treatment and in information technology, enabling the Human Genome Project to be completed several years ahead of schedule. These factors have also brought the cost of sequencing each of the basic components of the genome down from $2 to almost 1 cent in the last eight years. Scientists are even talking of the possibility of obtaining a person's complete genetic code at a cost of less than €1,000 in coming years, possibly months, as a result of the application of technologies such as biocomputing, sequencers and biochips.
This change will undoubtedly have a major economic and social impact and has aroused the interest of the Fundación de la Innovación Bankinter, in its desire to detect and monitor emerging trends, as part of the regular meetings of its "Future Trends" forum.

The context of the coming of personalized medicine

This process is taking place at a time of some commotion in our existing health models, especially in the pharmaceutical industry and in public healthcare systems.

Over recent years, spending on health care has increased steadily. It now accounts for nearly 15% of America's GDP and 8.5% of GDP in countries in the Euro zone, as compared to 11.9% and 7.4%, respectively in 1990. As a result of these increases, public health systems are experiencing major funding problems, given that, for example, countries in mainland Europe meet 75% of all healthcare expenditure.

Costs are rising in all areas of healthcare, but the fastest increase is in the pharmaceutical sector. The backdrop to this increase is a situation in which the world's pharmaceutical industry has seen a systematic reduction in the number of approved drugs, despite a threefold in the industry's R&D spending over recent years. It takes over $800 million and almost 15 years to develop a new drug.

To make matters worse, the public healthcare systems, driven by their own precarious situation, are putting pressure on the pharmaceutical industry. This pressure directly affects the profitability and even the viability of this important industrial sector.

This situation has resulted in a wave of mergers and take-overs in the pharmaceutical industry, leading to a doubling of the market share of the ten largest pharmaceutical companies to over 50% in 2002. This is a defensive concentration which has not, however, managed to substantially improve the performance of the industry, which in recent years performed notably below the average on stock markets.
In the midst of all this commotion in the healthcare system, society continues to bring pressure to bear for an improvement in healthcare quality, given that at present, many treatments are only 70% effective and secondary effects cause over two million hospitalisations every year, at an approximate cost of $100 billion, or around 1% of GDP. In addition, we are witnessing a rise in a many diseases for which there is no effective treatment, such as cancer, Alzheimer's disease and Parkinson's disease.

By its very nature, personalized medicine is going to substantially affect the different elements making up the healthcare system. It will modify these components both through the promise it holds out of bringing new more effective treatments with fewer side effects, and also through the additional investment and expenditure required for its introduction and maintenance. At the same time, the process of developing drugs is also going to change, making it possible to lower costs and favouring the marketing of new pharmaceuticals in areas already covered by other "traditional" ones. This will have a serious impact on the revenue of large pharmaceutical companies. Finally, it will affect individual people's life expectation and quality of life, with a corresponding impact at all levels, social and business-related.

The FTF's View of the Development of Personalized Medicine

FTF members believe that the development of personalized medicine is an inescapable reality; a new scenario which is being introduced steadily and quietly, but which in 10 to 15 years' time will be seen as a major revolution in the field of medical treatment and, thus in the health and quality of life of the wider population.

As a result of the FTF's deliberations, we have taken a base scenario of development of personalized medicine for the next ten years, whose key features are shown in the figure below. In this scenario, shared by the majority of the FTF members, the first practical advances would be made in under five years, although we forecast that it will take ten years before we see wider introduction in terms of the number of diseases and the people benefiting. Here it is important to stress that practically none of the experts is predicting a scenario of slower development, although a small group considers that change will come more quickly, mainly in terms of the number of diseases affected over the next five years.
Most Likely Scenario for Personalized Medicine according to FTF Members

**Base Scenario**

- **Therapeutic Areas**
  - Mainly Cancer
  - Safe effective pharmaceuticals according to genetic profiles
  - Individualised treatments with stem cells

- **Treatments**
  - Limited introduction and specialisation in private sector
  - Introduction in public health system, but only for certain isolated diseases
  - Primarily people with large economic resources

- **Introduction in Healthcare Service**
  - United States
  - Limited introduction and specialisation in private sector
  - Introduction in public health system, but only for certain isolated diseases

- **Benefiting Population**
  - Primarily people with large economic resources

- **Geographical areas**
  - United States

**Next 5 years**

- Greater number of areas such as diabetes, cardiovascular, psychiatric and neuronal diseases

**5 - 10 years**

- Preventative treatments based on genetic profiles
- Greater introduction in both public and private sectors but not covering all centres or all therapeutic areas
- Greater number of people, especially elderly people and patients with specific diseases
- United Kingdom, Mainland Europe and some other countries, such as Japan
As a result of this new situation, FTF members feel, major changes are in the pipeline: greater number of diseases with effective treatments; improvement in life expectancy and, above all in quality of life for individuals; increase in all items making up healthcare spending (related to GDP); reduction in the public sector's relative share in healthcare spending, and consequent increase in the role played by the private sector; emergence of new players and new business models in the pharmaceutical industry; and moderate increase in the number of drugs approved and greater profitability of these.

These changes will have a major social and economic impact, not only because of their substantial effect on countries' GDP, but also because their possible influence on the health and conduct of individuals will mean that all sectors of the economy will be affected to a greater or lesser extent. In view of this situation, each industry will have to assess the possible impact and the strategy it needs to follow depending on the scenario for the development of personalized medicine.

In order to facilitate this process of strategic deliberation, in a climate of great uncertainty regarding the speed at which these changes will be introduced, the forum has tried to identify indicators that will provide information and will be useful in monitoring the environment and consequent adaptation of business strategies (a summary of these indicators is given in the figure below).

Main indicators influencing the development of personalized medicine according to FTF members

![Diagram of indicators]

- Development indicators
  - Scientific/technological environment
    - Scientific and technological advances
    - Drug development process
    - Role of DEVCOs
  - Social and institutional environment
    - Social Pressure
    - Adoption by public healthcare systems
    - Government support

Importance/Weight
- >65%
- <35%
FTF members consider that technological factors will undoubtedly have the greatest influence on the speed of the process. Social and institutional aspects, however, will also be important and will therefore have to be taken into account as elements that could facilitate or hinder the introduction of the technological advances in the health-care system.

In conclusion, the advances in genome science and its basic application—known as personalized medicine—have already arrived and will bring about major changes that will affect not only the gigantic global pharmaceutical industry and models of public health care, but also the lifestyle and quality of life of society in general and, as a result, all business sectors.

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