Personalized medicine and biomarkers, a way of prevention and pharmacological development

The observation of drugs’ clinical use sometimes yields therapeutic ineffectiveness or even adverse reactions when commonly used doses are being administered.

It is estimated that adverse drug reactions cause between 5% and 10% of hospitalizations in Western countries. This is due to heterogeneous individual reactions to homogeneous treatments.

Thus, although the main goal of R & D in the pharmaceutical industry is to develop drugs aimed at improving patients’ life quality, it becomes a long and expensive process. The uneven effectiveness of drugs or adverse reactions has significant negative impacts in the following areas:

- Social: number of deaths that can be attributed to adverse drug reactions supplied, or to a lack of medication’s therapeutic efficacy.
- Health: increased use of health resources due to hospitalizations.
- Economic: increased health and social budgets, as the result of the two aforementioned impacts.

Progress on the relationship between the DNA sequence and drug response has identified new therapeutic goals, which consist of using this knowledge to understand the reason of the different responses of patients to drugs. This implies a paradigm shift: moving from a reactive and curative medicine to an individualized, predictive and preventive, and symptom oriented medicine.

The development of personalized medicine (PM) technologies is a key factor to predict chronic diseases, increase treatments’ efficiency and reduce the costs of worldwide healthcare systems. However, modern and individual medicines are not mutually exclusive but complementary. Their corresponding weights will depend on the existing knowledge about each pathology.

Biomarkers are a pillar of the PM. A biomarker is a chemical substance used as an indicator of a biological state to detect a disease (diagnostic markers), follow its evolution (prognostic markers) or choose a treatment (predictive markers). Biomarkers’ usefulness is multiple, because they can be applied to clinical treatment and also to drug development.

An example of a diagnostic marker is the classification of different types of leukaemia performed in the last century, which has led to improve its diagnosis and treatment. In this sense, the incorporation of biomarkers in clinical and pharmaceutical industry will give new names to many of the diseases that are unique, so that they will be classified into different types, and will allow for the development of specific therapies for each one of those diseases.
Impact on the sector

The scientific community uses a high number of biomarkers, though it is small when compared to those that might potentially exist or have not yet been discovered, documented or quantified.

The following are the pathological areas where more chances of finding biomarkers are detected: oncology, cardiology, neurology, and metabolic and immune system diseases. The severities of these diseases place biomarkers on the main agenda of regulatory authorities. In fact, the FDA (Food and Drug Administration, governmental agency of the United States of America, responsible for regulating health foods, drugs, vaccines, medical devices and biological products) has recognized the importance of biomarkers in pharmaceutical innovation and personalized medicine.

One of the great difficulties in the application of biomarkers is that their discovery is as hard as the subsequent drugs development. Although the scientific community has identified numerous potentially useful markers, many of them have incomplete or insufficient clinical data. Consequently, few are valid biomarkers as classified by the FDA.

Nevertheless, pharmaceutical companies are partnering to make biomarkers search more efficient and less costly. An example is the agreement between Roche and Evotec to develop biomarkers programs for therapeutic antibodies and small molecule inhibitors.

Another example of exploiting synergies between companies, this time in Spain, is the acquisition of Crystax by Oryzon Genomics. Oryzon Genomics is a biotechnology company specialized in new biomarkers and therapeutic treatments for oncologic and neurodegenerative diseases, and Crystax is a biopharmaceutical company specialized in the development of new therapeutic molecules for cancer treatment.

According to the latest report from Biocat 2011, public research in the biotechnology sector in Catalonia is focused on discovering new therapies and biomarkers to make early diagnoses and before they are deployed. Much of this research is done in the hospitals, where a third of Catalan research groups work.

There are 435 research groups consolidated in Catalonia\(^1\). The in vitro diagnostic has a considerable weight in their activities, which is due to the growing interest in biomarker discoveries to treat new diseases.

Furthermore, in oncology, Catalonia has a long value chain of biomarkers in centers and hospitals, and spin-off and pharmaceutical companies that perform research applied to diagnostic and new treatments\(^2\).

In 2011, 9% of GDP was devoted to health expenditures, and Spain was the number 21 in OECD countries in spending.

Spain stands number 6 of OECD countries according to drug spending.

The application of personalized medicine and the development of biomarkers may decrease drug spending.

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\(^1\) Situation of biotechnology, biomedicine and medical technologies in Catalunya. Portrait of a moving industry. Biocat 2011.
\(^2\) http://oncocat.org/
Impact on professional profiles

Personalized medicine (PM) affects the whole substrate of medicine. However, since the decodification of the human genome, the PM is developing unevenly in medical fields. In some of them, clearly positive results are being obtained, such as in breast cancer tumours, which have a number of special biomarkers; in other fields, fewer results are yielded.

Thus, the PM is on the way to become a reality that will affect the whole set of health system actors: legislators, patients, medical professionals, managers and researchers.

On the legislative front, lawyers applied to medicine will have a new field of intervention, which requires additional training in this area, especially with the protection of patient’s rights in relation to the ethical challenges posed by genetic analysis techniques, and to the storage and use of samples with personal information.

From a health care perspective, the medical community must treat diseases integrally with the group of specialists that may be involved in a particular process, organized in multifunctional units capable of holistically approaching each patient’s case.

On the other hand, new hospital units may also come up, mainly in clinic hospitals, requiring specialists in genetics and biomarkers who are able, for example, to perform genetic tests (tests to diagnose, on the base of genetic analysis, vulnerability to certain hereditary diseases).

In the health care field, technical staff capable of implementing quite sophisticated techniques and being in constant evolution will be necessary. It will also require health professionals with knowledge of genomic medicine, enabled to interpret the results in clinical terms, and genetic counselors to support health professionals in this area.

From biomedical research, the importance of transferring immediately the results to clinical practice will require better synergies between researchers and health care professionals. Moreover, this trend may increase the demand for profiles on the field of advanced therapies, such as specialists in systems biology or in pharmacogenetics.

Health management and its professionals will also face new challenges with the PM. Managers will have to find sufficient evidences that investing in biomarkers is economically beneficial both for the hospital and the patient, and this fact will force them to think long run, change certain management routines, and redirect resources from areas with little value projects to others with more added value projects.

On the other hand, the tests performed in PM are expensive, so that hospitals will have to centralize experts in PM technologies and biomarkers in laboratories endowed with the infrastructure and knowledge necessary to improve efficiency and effectiveness.

All in all, the generalized implementation of PM in the health system will require a huge training and dissemination effort not only to health professionals but also to managers, media, and all citizens, who will be the main beneficiary of this new concept of medicine.

More information about the industry is available on the Barcelona Treball website

Market >Industries > Biotechnology and biomedicine

This section of the website contains a report on the industry covering aspects on employment issues, where you will be able to take a look at occupational fiches for various job profiles and learn the main resources needed to find a job in the industry.