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Title

Speeding up the Development and Implementation of Personalized Cancer Therapeutics - the case of Herceptin® in England

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Abstract

New technologies and advances in science play an important role in many aspects of improving healthcare provision and offer new and better ways of solving key health problems. Over the last decade it has become possible to diagnose and treat a number of diseases – including various types of cancer – earlier, and with higher precision than was possible before. However, the uptake of the first modern cancer therapeutics in Europe has been slower than expected by involved actors, and uneven between countries. This paper aims to give insight into the underlying factors in this poor uptake trajectory and to systematically analyse how biopharmaceutical innovation works and which factors promote and hinder it by applying the Technological Innovation System (TIS) framework. This is done by studying the dynamics of seven key activities that have influenced developments around the breast cancer drug Herceptin® , and its companion diagnostics in England. The study provides several lessons for practitioners to take into account when developing policies for the acceleration of the development and diffusion of modern cancer therapeutics.

One of the biggest challenges in society today is the provision of a better quality of life to the population as a whole, as well as to each individual. Quality of life does not only include wealth and employment, but also extends to the overall wellbeing of an individual including health. For already more than ten years, personalized medicine (commonly known as the practice of emerging medicine that uses the patient's genetic profile to make treatment decisions) has made it possible to diagnose and treat a variety of diseases – including various types of cancers - earlier and with higher precision than was possible before.

These developments are expected to expand doctors' power to customise therapy for each individual, maximising the effectiveness of drug treatments and minimising their side effects (Bono de, et al. 2010).The concept has great promise for medical practice and health related policies, but until now, progress towards realising the potential of personalized medicine in Europe has been problematic. The time needed from identifying the molecular target until bringing the drugs to the patients in clinics is longer than predicted and differs significantly between countries, England being one of the slowest in Western Europe. Although basic science is always ahead of practice in the medical field, the current gap in the area of personalized medicine is considered by some researchers as rather large (Aspinall, Hamermesh 2007; Bono de, et al. 2010; Borden, et al. 2010) and there are still a number of unsolved technological, regulatory and reimbursement issues in health policy that need to be clarified before society in

Europe can fully benefit from the new medical solutions that modern cancer therapeutics have to offer.

Through insight into the dynamics of the development and diffusion of one of the first personalized cancer therapeutics (Herceptin®) and its' companion diagnostics, in England, this paper aims to find answers as to how to understand the development and diffusion of personalized cancer therapeutics and diagnostics over time. By doing that, it also tries to define strategies/policies/governance to improve the implementation and diffusion of these therapeutics in the modern healthcare system in Europe.

It is important to recall that "personalized medicine", does not refer to one specific technology, but rather consists of a combination of the completion of the human genome sequencing project and new technologies, such as high-throughput next-generation sequencing, combinatorial chemistry, a host of "omics" tools" (e.g. genomics, proteomics, metabolomics) and cell technologies that help to detect, manage and predict different diseases. Over the past decade, the concept of using all these different new technologies to "personalize" medicines and diagnostic technologies based on genetic characteristics has advanced rapidly. This has been drawing the pharmaceutical industry closer to the world of diagnostics more than ever before (Groves, et al. 2011) and making these different, but at the same time interrelated technologies more co-dependent of each other.

Making new drugs and diagnostic tests available for targeted cancer therapeutics in the clinical setting involves a complex sequence of events and various steps that connect research and development of testing approaches to market access, pricing and reimbursement. The majority of included actors are still adjusting themselves to this new paradigm of healthcare. The Systems of Innovation (SI) approach does not require the system in focus to be fully-developed. Instead, it may be only in the developing stage with weak interactions between its different components (Bergek, et al. 2008), and therefore it is well suited to the study of this new technological field. In this study the Technological Innovation Systems (TIS) framework (Hekkert, et al. 2007; Negro, et al. 2007) which is part of the wider Systems of Innovation theoretical school is applied. This enables to study the characteristics of the system associated with specific emerging technology fields and analyses its strengths and weaknesses as well as its dynamics (Jacobson, Johnson 2000).

The objectives of this paper will be reached by studying the dynamics and performance of TISs around personalized medicine, in particular regarding the breast cancer drug Herceptin® and its companion diagnostics in England. For the Innovation System, the

drivers and barriers for system performance will be denoted, as well as the set of structural factors relating to them. The outcomes will then be analysed and possible policy paths will be presented which could improve the functioning of the system and accelerate the development and diffusion of modern cancer therapeutics and their diagnostics in the England. In this drug specific case study, various methods of traditional TIS analysis (Hekkert, et al. 2007) will be combined with some elements from Innovation Ecosystems framework, as the concept of co-dependence of different technologies is heavily conceptualised in an Innovation Ecosystems framework that helps to analyse the interrelatedness of therapeutic and diagnostic technologies.

The main research objectives of the study:

As there is no systematic overview available of the actors involved in the exploitation of Herceptin® and its accompanying diagnostics in England, the first objective of this paper is to obtain an overview of the key actors in the respective country. Secondly, this paper is looking for the reasons behind why the uptake speed and rate of modern cancer technologies was very low in England during the launch of Herceptin® in 2002, therefore the objective is to provide an insight into the range of key processes related to these applications, which stimulate or hinder the development and diffusion of targeted cancer therapeutics England.

Expected results:

- Firstly, based on the empirical findings, the paper aims to support policy makers in their decision making process by creating a more favourable environment for the adoption of modern cancer therapeutics and diagnostics. Also, the research will try to identify some of the hurdles for the private sector in adopting the personalized medicine approach in their drug and diagnostics development process in oncology and will try to offer some possible solutions to overcome current bottlenecks.
- Secondly, this study not only looks at the development and diffusion of modern cancer therapeutics from a Technological Innovation Systems perspective, but it also analyses its interrelatedness of diagnostic technologies. The concept of co-dependence is heavily conceptualised in an Innovation Ecosystems framework, however there have been no studies until now that have tried to look at this aspect from a TIS perspective.
- Thirdly, the majority of TIS studies conducted until now have focused on one specific technology only. This study is taking into account one specific technology and the complementary associated technologies (theranostics: combined therapy

and diagnostics). Owing to the dependencies between multiple technologies, its analysis may lead to new insights compared to a technology specific study.

- Last but not least, this paper contributes to the Systems of Innovation theoretical field through replication. As it applies the TIS concept and IS approach to different technology fields outside the domain of sustainable development - pharmacogenomics, it serves as a validation of the current TIS framework that lacks empirical studies from other fields outside the sustainable energy sector.

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