

Background Information

Roche Personalised Healthcare – In Brief

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Background

Personalised Healthcare is based on the knowledge that different patients with the same clinical diagnosis may respond to the same treatment in different ways. While a certain drug might be highly effective for one patient, the same drug might not show the same desired results in another patient, despite the same diagnosis. Disease-related, as well as disease-independent, individual characteristics influence the way drugs work. To treat all patients diagnosed with a certain disease using a broad-brush approach disregards these individual differences.

In other words, conventionally practiced healthcare has not been as effective as it could be. Too many patients receive treatments that are not advantageous for their particular disease scenario. And, in some cases, these treatments might even cause adverse reactions. Roche's Personalised Healthcare strategy aims to provide medicines and diagnostic tools that enable tangible improvements in the health, quality of life, and survival of patients. It is an approach which capitalizes on the extended knowledge of the molecular basis of diseases and how medicines work, as well as on our increasingly sophisticated understanding of patient differences.

Roche Pioneering Personalised Healthcare

Within the past few years, Roche has embarked on a systematic approach for the discovery and creation of medicines, interweaving diagnostic and pharmaceutical expertise to pave the way for Personalised Healthcare. We have already begun to provide healthcare professionals with more powerful diagnostic tools and targeted treatments that are based upon new insights into how disease arises at the molecular level. By providing new options, Roche aims to tailor treatments as closely as possible to patients' needs. As one of the world's leading healthcare companies, we are uniquely positioned to enable and deliver Personalised Healthcare, set apart by our combined strengths in pharmaceuticals and diagnostics.

Benefits of Personalised Healthcare

Personalised Healthcare has enormous potential to add true medical value to healthcare by providing targeted treatments, increasing the quality of life, and being more cost-effective. While the full potential of Personalised Healthcare will only be realized in a stepwise fashion, we already have a number of successful examples that show a clear shift away from the “one size fits all” approach, towards more targeted medicines and response-guided therapies.

By taking into account the different characteristics of patient sub-populations and their disease specificity (e.g., cancer subtypes), we can demonstrate that in many cases Personalised Healthcare:

- Improves understanding of disease diversity and allows to stratify patient sub-groups
- Increases efficiency and efficacy in R&D
- Helps to avoid disadvantageous and/or unnecessary treatment, thereby enhancing cost-effectiveness
- Supports the development of safer and more effective treatments, thus reducing the risks and costs of side effects
- Provides the diagnostic tests which help identify patient groups most likely to respond to a specific treatment
- Improves medical outcomes for patients and quality of life

Challenges in Developing Personalised Healthcare

Personalised Healthcare holds great promise for patients; expectations are high. And, it is not a new concept – it has evolved over time and will continue to do so (e.g., measuring blood glucose levels to determine the right insulin dose). Carrying out the necessary research is a complex undertaking and will justifiably take time.

But while it will not always be possible to develop Personalised Healthcare solutions for every condition, or to improve every current care standard, Roche is fully committed to doing everything in its power to make this potential a reality by developing as many new diagnostics and treatments—for as many patients—as possible.

PHC - Already a Reality Today

Oncology: Selected patient sub-group and tailored treatment in breast- and gastric cancers

Herceptin is a humanised antibody, designed to target and block the function of HER2, a protein produced by a specific gene with cancer-causing potential. Herceptin activates the body’s immune

system and suppresses HER2 to target and destroy the tumour. Herceptin has demonstrated efficacy in treating both early and advanced (metastatic) HER2-positive breast cancer.

In January 2010 the European Commission has approved Herceptin (trastuzumab) in combination with chemotherapy for use in patients with HER2-positive metastatic stomach (gastric) cancer. The approval is based on results from the international ToGA trial, which showed that treatment with Herceptin significantly prolongs the lives of patients with this aggressive cancer.

Virology: Hepatitis – a disease area where Personalised Healthcare is a reality

The Hepatitis B and C viruses (HBV, HCV), which are commonly transmitted through blood-to-blood contact, cause acute and chronic liver disease, potentially leading to liver failure, cirrhosis and liver cancer. Worldwide, about 400 million people are thought to be chronically infected with HBV, a highly infectious virus that is responsible for an estimated 1 million deaths annually. More than 170 million people worldwide are infected with HCV, and 3–4 million new cases occur each year. Hepatitis C is the primary cause of liver transplantation.

Response Guided Therapy for Hepatitis C patients - Hepatitis C infection (HCV)

Roche provides Pegasys and Copegus combination therapy for chronic HCV infection and its cobas diagnostic tests can be used to determine the duration and dosage of therapy. The results of these tests allow treatment to be tailored to specific sub-groups of patients, because physicians can identify the sub-type of infecting hepatitis C virus and the amount of that virus in the patient's blood.

The regular course for treatment of Hepatitis C infection is 48 weeks. But advances in understanding the infection and the ability to identify different HCV-subtypes allows for the adjustment of treatment duration; for example, cutting the treatment duration in half (from 48 to 24 weeks) for patients carrying sub-types 2 or 3. For the same subtypes, an even further shortened treatment course (16 weeks) exists for those patient sub-groups who have low virus levels before starting treatment, and who also clear the virus from the blood within their first 4 weeks of treatment. This treatment course has been approved since 2008. These adaptations are very important for patient care, as they reduce exposure to active medication and potential side-effects.

The treatment of Hepatitis C infection is a leading example of progress made in modern patient care. This virus, only identified in 1988/89, causes a chronic disease of the liver leading to malfunction or even liver failure in many patients.

Infection with the Human Papilloma Virus (HPV)

One of the most groundbreaking medical discoveries of recent times is that persistent infection with certain types of human papilloma virus (HPV) can progress to pre-cancerous neoplasia or cervical cancer in women. Early detection of high risk infection allows prevention and early treatment, thus improving outcomes in cervical cancer. By providing physicians with a practical way to apply this knowledge, Roche's diagnostic tools help to detect infection with the HPV types that have the highest risk of progressing to cervical cancer. Moreover, Roche is helping to deliver tangible benefits to patients - early detection of high-risk HPV infection enables earlier treatment and thus saves lives.

PHC in the Pipeline:

Cancer – Melanoma

One example for promising pipeline projects is a candidate drug and diagnostic test in co-development for metastatic melanoma. In approximately 50% of melanoma patients, a mutant gene carried in the tumour itself, BRAF V600, appears to be responsible for uncontrolled cell growth. Roche, together with its partner Plexikon, is developing RG7204. In parallel, Roche Molecular Diagnostics has developed the cobas BRAF V600 Assay to identify patients carrying the mutation, thus enabling the investigators to identify those patients that truly will benefit from the treatment with RG7204.

Outlook

Expertise in molecular biology and clinical research as well as both diagnostic and pharmaceutical in-house experience will allow Roche to continue driving Personalised Healthcare forward. Taking advantage of its unique position, Roche is already delivering Personalised Healthcare approaches. Personalised Healthcare is a key element of the company's core strategy, and will benefit patients who are in need of better or new medications.

Roche has begun to deliver on its promise. Personalised Healthcare has become a reality and will continuously gain momentum going forward.