

Roche Position¹ on Personalised Healthcare

Background

Roche Personalised Healthcare (“PHC”) is based on the observation that patients with the same diagnosis may react to the same treatment in different ways: While a drug can be highly effective for one patient, the same drug might not show the desired results when given to another patient with the same diagnosis. Disease-related as well as disease-independent individual characteristics influence the way drugs work with the consequence that conventionally practiced healthcare is not as effective as it could be. Considerable numbers of patients still receive treatment that is suboptimal for them; in some cases, treatment may even cause adverse reactions. PHC has the potential to further improve the efficacy and safety of treatments. This is an approach which capitalises on our increasingly sophisticated understanding of differences among patients, the molecular basis of disease and of how medicines work. By taking the individual characteristics of patients and their diseases (e.g. cancer subtypes) into account, PHC has the potential to:

- Further improve understanding of disease diversity and subtypes;
- Identify patients who are at increased risk of suffering from a certain disease and create opportunities for preventive measures before the disease develops;
- Allow a more precise diagnostic and prognostic assessment of patients with the chance of earlier and more specific treatment;
- Provide the diagnostic tests which help identify patients who are most likely to respond to a specific treatment – helping to avoid treatment without benefit (“trial-and-error prescribing”);
- Allow a faster, less burdensome and less expensive drug approval process by conducting trials on smaller patient subgroups qualified by specific biomarkers;
- Aid in the development of safer treatments, thus reducing the risks and costs of adverse events and thereby improve the overall cost-effectiveness of care.

This PHC-approach also supports several of the United Nations Sustainable Developments Goals (SDGs), in particular SDG3. This goal aims at ensuring healthy lives and promoting well-being for all.

In recent years the knowledge of the human body and of disease mechanisms has improved considerably, leading to the conclusion that PHC approaches will become increasingly important. PHC has evolved over time and will continue to do so, incorporating the increasing quality and quantity of molecular information will take PHC to a next level. While significant progress has been made already, carrying out the necessary research is an increasingly complex and expensive undertaking and will take time. Innovative companies like Roche face a complex external

¹ Pertains to SDGs 3 and 16



economic environment where innovative PHC approaches are not always adequately incentivized and rewarded.

Stakeholders' Expectations and Concerns

Innovative healthcare companies are expected to explore the potential of PHC in order to discover and develop novel and better medicines that are effective and have fewer side-effects, innovative diagnostic products and medical devices as well as services of high quality addressing current unmet medical needs. Stakeholders' expectations regarding the advantages and benefits of PHC related products and services are high. As with any other new intervention, they expect that PHC solutions demonstrate adequate effectiveness and safety before they are applied in routine care. In addition, patients expect to be adequately informed by well-trained health professionals about the benefits and risks of available PHC solutions.

Stakeholders' expectations are sometimes linked to concerns related to (i) the high costs regarding research and development of PHC solutions and to (ii) the affordability of innovative PHC products and services. Patients request that personalized medical services are adequately covered by insurance companies and public health care systems.

Roche's Position

Roche, as an innovation-driven global healthcare company, is pioneering PHC solutions with passion. Roche is convinced that PHC is key to delivering further improvements in the practice of medicine. PHC will enhance the efficacy and safety of medicines and will thus improve patients' lives, their health, quality of life and survival. Roche's prime objective is to provide PHC solutions which deliver superior options for diagnosis and treatment to clinicians and patients.

Over the last few years, Roche has embarked on a systematic approach that interweaves our diagnostic and pharmaceutical expertise to pave the way for PHC. Our goal is to provide healthcare professionals with more powerful diagnostic tools and with targeted treatments based upon new insights about molecular markers that allow a more precise determination of the risk of certain diseases as well as drug efficacy and safety.

While the full potential of PHC will only be realized in a stepwise fashion, Roche has already developed a number of successful examples², showing a clear shift away from the "one size fits all" approach. In 2015, our medicines approved with a companion test contributed 26% of the Pharma division's sales.

² For examples, please see : http://www.roche.com/about_roche/personalised_healthcare.htm



In promoting development and application of PHC solutions, Roche takes into account the expectations and concerns of key stakeholders:

- In the selection of disease areas for the development of new personalised diagnostic and therapeutic interventions, Roche carefully considers patients' health needs.
- Roche makes sure that PHC solutions are adequately tested for efficacy and safety before they become available on the market. Roche starts this work early in the research and development process of new medicines and diagnostics in order to ensure that insights generated from PHC approaches can be integrated into project plans in a timely fashion. Roche is aware that the increased knowledge about genetic predispositions and predictive biomarkers provides challenges both for health care professionals and patients. Roche is therefore committed to contribute to the education of health care professionals concerning the potential and implications of PHC solutions, so that they are able to adequately inform patients about the opportunities and limitations of PHC solutions.
- Roche acknowledges that public and private payers have an increasing interest in containing healthcare costs due to limited financial resources. Therefore, Roche will contribute to gather medical and economic data to provide further evidence that PHC adds value to the healthcare system by providing innovative and cost-effective medical solutions for relevant unmet patient needs. Roche expects that PHC solutions and services, in line with other health technologies, will be assessed in a transparent, open, fair and consistent process and that the value created will be adequately rewarded by health care payers.³ Health systems reforms that promote value-based reimbursement for innovative, patent-protected diagnostic and therapeutic products will further strengthen the research and development environment for PHC.

Outlook

Combining our strengths in pharmaceuticals and diagnostics, Roche is uniquely positioned to make PHC a reality. Roche has the expertise in molecular biology and clinical research and the experience and tools of a large and successful diagnostic and pharmaceutical company in-house. We are committed to the systematic pursuit of PHC approaches throughout the lifecycle of our products. Roche is equally committed to entering into a dialogue about the value created by PHC solutions. Roche actively encourages this dialogue with all its stakeholders being fully convinced that PHC has enormous potential to make healthcare better, safer and more cost-effective.

This position paper was proposed by the Corporate Sustainability Committee and adopted by the Corporate Executive Committee on December 9, 2009 and entered into force the same day.

It was reviewed in April 2020.

³ See also Roche Position on Assessing the Value of Roche Products and Services