

Personalised Healthcare – a key element of our Group’s strategy

Roche was one of the first companies to recognise the potential of personalised healthcare (PHC). Today PHC is central to our Group’s strategy. We see it as a key enabler helping us increase our success rate in drug development and bring more clinically differentiated medicines to patients. In a recent roundtable, Severin Schwan (CEO Roche Group), William M. Burns (CEO Pharmaceuticals Division) and Jürgen Schwiezer (CEO Diagnostics Division) talked about Roche’s PHC strategy and its implementation, how PHC will create value for our healthcare stakeholders and how it will create value for Roche.



William M. Burns, CEO Pharmaceuticals Division
Severin Schwan, CEO Roche Group
Jürgen Schwiezer, CEO Diagnostics Division

Roche is actively pursuing personalised healthcare, and has made it one of the cornerstones of its strategy of innovation. Why? What is the promise of personalised healthcare?

S. Schwan: First, it’s not by chance that Roche has taken a leading role in personalised healthcare. Our Pharmaceuticals and Diagnostics Divisions both began investing very early in molecular biology, and the expertise this has given us puts us in a strong position today to move personalised healthcare forward.

W. M. Burns: Science’s understanding of disease at the molecular level is growing almost exponentially, opening up real opportunities to treat illnesses more effectively. Right now, these opportunities may lie largely in learning to adjust the use of today’s medicines to better fit the needs of particular patients – possibly with the help of new diagnostics – but ultimately the aim is to design the treatments of tomorrow. So the promise of personalised healthcare is very much rooted in science. If we can intelligently bring together true innovation in medicine and better tracking of disease, we’ll be able to do a better job of tailoring treatment options to different patient populations and identifying which patients are most likely to respond to a particular option. This is important at a time when the clinical hurdles to bringing new medicines to market are getting higher.

J. Schwiezer: Too often medicines either don’t work or produce unacceptable side effects. Depending on the disease and the drug, response rates can be as low as

20%. So for patients, the promise of PHC is higher response rates and fewer patients needlessly exposed to the risk of side effects, while for governments and other healthcare payers, it's the promise of being able to use resources more effectively – paying for interventions that provide benefit, not for interventions that don't.

Diagnostics have a pivotal role to play here, though this isn't anything new, really. For decades doctors have used blood sugar tests to determine the insulin needs of their patients with insulin-dependent diabetes. Viral load monitoring and viral genotype testing, particularly for HIV and for hepatitis C, are another, more recent example of diagnostics guiding therapy. These tests measure the amount of virus in a patients' blood and can detect viral resistance to particular medicines. This information helps doctors decide how long and how aggressively to treat a patient's infection, what drug combination to use, and when a change of drug or dosage is needed.

S. Schwan: I fully agree with Jürgen that, in a sense, personalised healthcare is nothing new. Doctors have always tried to fit the therapy to the patient if possible. But what's happened more recently is that we've begun to go a level deeper, if you will. We're now exploring the biology of disease and treatment at the molecular level. In drug research, we're using powerful new technologies to select molecules in the body that could make good drug targets. And we can design clinical trials in a more differentiated manner. The progress in science is opening up opportunities to tailor treatments to specific patient populations better than ever before.

W.M. Burns: Hepatitis C, which Jürgen touched on briefly, is a good, real-life example of how we've made medicine more personalised. Hepatitis C was discovered only about 18 years ago. Now, with the help of genotyping, we're able to tell patients within 12 weeks whether they'll respond to treatment with Pegasys. In patients with HCV genotypes 2 to 4 we know a short course of therapy is likely to be successful. And a

72-week course of therapy with Pegasys was just recently approved for genotype 1 non-responders. So we really have personalised the options available to some patients through a combination of innovative medicine, genotyping, and viral load monitoring.

However, virology has proven to be one of the more 'predictive' disease areas. In others, like oncology, we have a wealth of knowledge, but finding clinically relevant biomarkers to track is not as easy. Our targeted breast cancer medication Herceptin and the HER2 companion tests to identify patients likely to benefit from Herceptin are still more the exception than the rule. We're still at a very early stage of discovery, but science is definitely pointing in the direction of PHC. We need to harness the science and make it work for patients. If we don't, we'll be missing out on an opportunity to capitalise on one of our greatest assets – our special combination of strengths in pharmaceuticals and diagnostics.

S. Schwan: The expertise we've built up over the years in pharmaceuticals and diagnostics gives us a sustainable competitive advantage. It's not something other companies can duplicate easily or quickly. The depth and breadth of our pharma and diagnostics capabilities make us ideally equipped to be at the forefront of PHC. The question is not whether we can lead, the real question for us is: Do we want to lead? And the answer is yes.

W.M. Burns: Given the complexities that we know we are having to address within one company, it's hard to imagine a pharma company dealing with a separate diagnostics company and finding a way to just 'plug and play'. If anything, the complexities are likely to be magnified. Our shared libraries of clinical samples, our ability to design a pharma study that could also validate a diagnostic marker – if we join things up correctly, there are any number of opportunities for us to create a sustainable competitive advantage for ourselves.

How can personalised healthcare create value for Roche?

W.M. Burns: From a Pharma perspective, our goal is to achieve the kind of clinical differentiation that can make a difference in the practice of medicine – and to be able to make a health economic case for our products. Being able to distinguish subsets of patients likely to respond to a medicine, or subsets who shouldn't even try it, is one way to enhance our chances of achieving clinical differentiation. Obviously, the ideal is a pharmaceutical paired with a companion diagnostic, but we need to be realistic in our expectations. We've had successes in HIV and hepatitis, but today's science isn't going to translate overnight into more drug-diagnostic combinations. Pursuing such projects, even when not immediately or entirely successful, can unlock profound value for the organisation, however, so we need to continue focusing on them.

J. Schwiezer: Roche Diagnostics has two roles. One is to create novel instruments and assays for the 'in vitro' diagnostics market. We're the world leader at this. And our other very important job is to support the Pharmaceuticals Division in achieving their goals, by providing some of the tools they need in the drug discovery and development process. At Roche Diagnostics we've taken steps to fill both roles better, including the acquisition of technologies giving us a wider range of the capabilities we need to be a full-service partner to Pharma.

Again, the fact that we're all one organisation gives us the distinct advantage of being able to work together from early discovery to launch. And for our shareholders there's the additional advantage that they benefit from the intellectual property generated during discovery and development regardless of which division commercialises it.

What are the hurdles and roadblocks we have to overcome to make PHC happen?

S. Schwan: The biggest challenge I think is the complexity of the science. It's not easy to develop a truly differentiated medicine or to find the biomarkers to guide its use. But I think we now have the building blocks in place to make PHC happen. I see two important areas where we've made progress. One, as Jürgen mentioned, is in extending our portfolio of diagnostics technologies, in part by acquiring companies like NimbleGen, 454 Life Sciences and, more recently, Ventana. And I think the second element that demonstrates our commitment to PHC is the organisational alignment we've carried out over the last two years, in both divisions, to support smooth, integrated cooperation between Pharmaceuticals and Diagnostics. Again, the building blocks are in place; now it's time to make PHC happen – in the interest of the patient.

People are different – so are diseases

People can react very differently to the same medications. Some patients will benefit, while others only experience unwanted side effects. Today, the response rates to treatments vary from 20% to 75%, depending on the drug and the disease. At Roche we're committed to using our expertise in molecular biology to gain deeper insights into disease and differences between patients. This is part of our broader commitment to personalised healthcare (PHC). We are seeking better drug targets and clinically relevant biomarkers that will one day enable doctors to tailor treatments more closely to patients' needs and predict which patients will benefit and which ones won't. This is the essence of PHC. In areas such as oncology and virology, patients are already benefiting from safer, more effective treatments thanks to our commitment to PHC.

