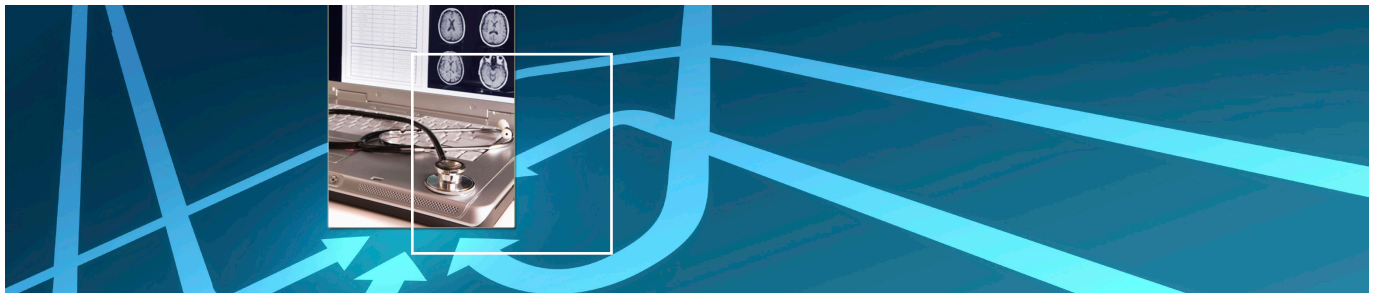


The Curing Company

Finding a New Business Model to Relaunch the BioPharma Industry



Highly successful drugs, sometimes known as blockbusters, have a great impact on healthcare as they treat a large number of patients, and are most frequently indicated in common, often chronic conditions. This guarantees a high level of usage and therefore a profitable drug, however the premium placed upon producing such drugs can result in smaller conditions being neglected. Due to the private nature of the pharmaceutical industry, and because there is more money in developing 'blockbuster' drugs capable of treating common diseases, the healthcare industry faces numerous challenges as rarer diseases which may be just as life-threatening see fewer drugs entering trials. In this article, we propose a new business model using the available technologies to achieve the necessary transformation.

Traditionally, clinical diagnoses and treatments have focused on diseases and cures. For every ailment, one or several treatments were developed, which aimed to treat all patients diagnosed with the disease in case, with the individual patient not taking part in the decision process.

Although this "one size fits all" model has served humanity well, it is slowly showing its limitations. First, each patient is unique, as is each disease or affliction case. By treating all cases as the "default case," medicine ignores individual patient specificities and disease diversity. Second, this approach limited medicine to a strictly reactive operating mode: the patient gets sick, seeks treatment, a cure is identified and the patient is treated. Clearly, this is very inconvenient for the patient, as he or she is required to get sick first. "Prevention is better than cure" was never more appropriate.

Over the last decade, the above considerations, combined with key technological breakthroughs (such as molecular profiling, genetic testing and proteomics) have led to the notion of "personalised medicine." It is a medical model, emphasising the customisation of healthcare, with all decisions and treatments tailored to the individual patient. Recently this has involved the systematic use of genetic or other patient-specific information to optimise both therapeutic as well as preventive care.

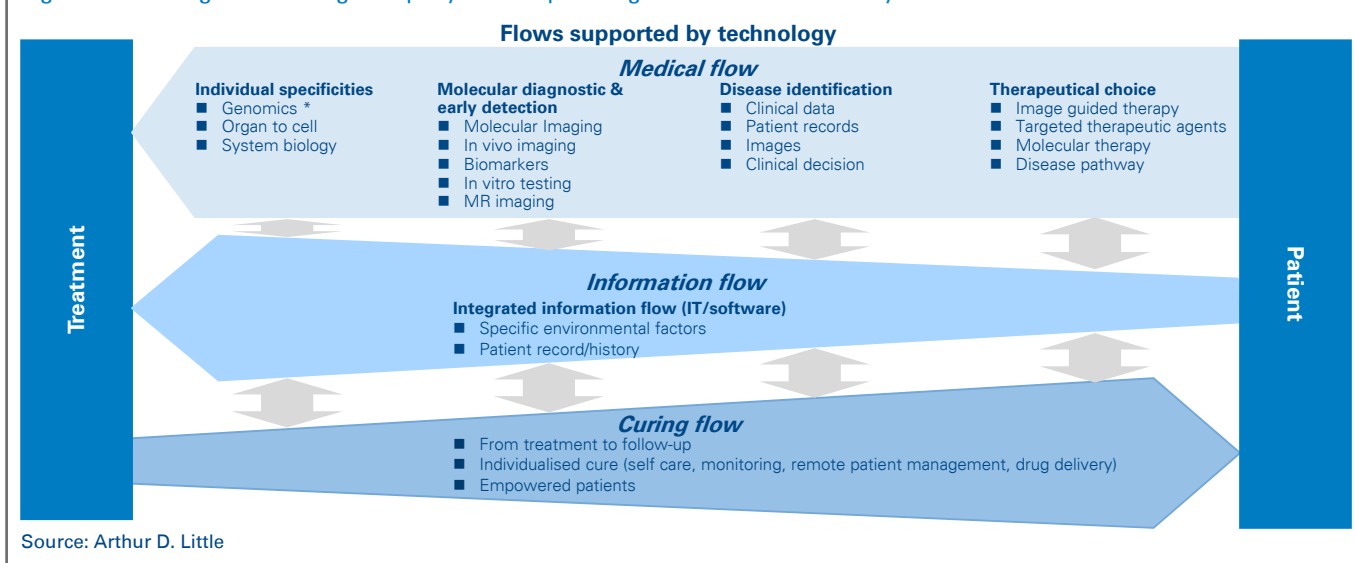
The rise of personalised medicine and patient centricity has given way to the idea of the "Curing Company": the company which looks after the entire two-way link between the patient and the treatment (see Figure 1 overleaf).

This link consists of three important flows:

- A medical flow, including the disease identification and the diagnostic, taking into account the individual specificities
- An information flow, starting from the patient, yielding indispensable information based on the patient's individual (molecular/genetic) specificities which are the basis for molecular diagnostics and therapeutical selection;
- A curing flow, providing the therapy, cure or treatment to the patient, but also the follow-up on the patient's adherence and responsiveness to the treatment

This interaction between patient and treatment, facilitated by the "Curing Company," obviously requires significant technological support. Key technology pillars to enable this interaction between patient and treatment include instrumentation, biochemistry and software/IT support. Lately, significant progress has been made in developing the technology required to develop this patient-treatment link. The Laboratory for Personalised Molecular Medicine (LabPMM) in San Diego for instance, was founded in 2007 to identify specific mutations in genes linked to clinical outcomes in patients with leukaemia and lymphoma (e.g. FLT3 and NPM1). The organisation actively collaborates with and assists academic centres and hospitals in the development of patient-specific molecular tests from patient tumour DNA samples. The ultra-sensitive tests are used by leading cancer treatment centres worldwide to monitor residual disease and treatment. Other initiatives in this direction include the Harvard Partners Centre for Genetics and Genomics, launched in recognition of the excitement of the Human Genome Project

Figure 1. Building « the Curing Company »: retro planning the Healthcare industry



and as an early commitment to the importance that genetic and genomic knowledge would play in human health.

Science’s rapid advances in deciphering the patient’s individual specificities, doesn’t merely enable a more targeted treatment selection. More importantly, it allows for targeted prevention. Methods such as proteomic profiling, metabolomic analysis or genetic testing can be used to assess a patient’s risk factor for a number of conditions, and to tailor individual preventive treatments. Although the focus may typically be on secondary prevention (attempting to diagnose and treat an existing disease in its early stages, even before it establishes itself noticeably in the patient), primary prevention opportunities may also be included (avoid the development of a disease for which the patient has a high risk factor).

At the other end of the Curing Company cycle, business is also getting involved. In January 2011, for instance, GE and Intel created a new company (50/50 joint venture), Care Innovations, which aims to leverage technology for chronic disease management and facilitated independent living, thus targeting the curing stream flowing back towards the patient. It is clear that in both streams, advanced (tele)communication technology will be required to realise personalised medicine’s true potential. “mHealth”¹ has in this context been hailed as the next major development for mobile networks operators (MNOs), applying mobile technologies in healthcare systems that enables the transformation from physician-centric to patient-centric healthcare delivery (see Figure 2).

Such examples clearly illustrate however, that companies are still targeting fractions of the Curing Company cycle, e.g. genetic decoding, therapy selection, cure follow-up etc. So far, no one has tackled the entire Curing Company cycle, even though the

Figure 2. Real-life Example: Personalised Hepatitis Therapy by Roche

Personalized Healthcare Example – Roche’s Hepatitis Therapy

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. An additional 170 million people are infected with HCV, with 3-4 million new cases occurring each year. Hepatitis C is the primary cause of liver transplantation.

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 level 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.

Source: Roche

advantages of profiling oneself as a “holistic” Curing Company are significant. The Curing Company concept offers “value based healthcare” (VBHC) maximising value—that is, outcomes divided by costs, for the patient and the social security system as well as the providing companies involved. Furthermore it holds opportunities for diversification and market penetration. Offering the full closed patient-treatment loop would provide companies with an invaluable competitive advantage. This would iteratively confirm and

1 For more details, please refer to Arthur D. Little viewpoint “Capturing Value in the mHealth Oasis”

2 The Curing Company

Figure 3. Key Challenges in the Pharmaceutical Industry

Back to the Core Science	Focus on Patients	Technology Integration
<ul style="list-style-type: none"> ■ Uncertainty over the pipeline;; Blockbuster growth is insufficient ■ Trend towards personalised medicine: Development of the niche-buster model ■ Increased speed of "fast follower" : Closer innovation and second-generation ■ Reimbursement and cost pressure: Shift towards long-term cost-benefit analyses ■ Growth of biochemistry: Barrier against patent loss 	<ul style="list-style-type: none"> ■ Search for a novel business model: "beyond the blockbusters" ■ Increased focus on health economics: Delivering benefits ■ Increased patient information transfer: Offer better service and avoid malpractice ■ Change in key patient types: Stay close to respond faster ■ Patient focused treatments and applications: Personalised medicine 	<ul style="list-style-type: none"> ■ From fully-integrated to virtually-integrated: Integration to deliver results ■ New emerging technologies: Providing new and more precise cures ■ Integration of systems: Using data to optimise cure ■ Rise of new manufacturing technologies: Increase manufacturing flexibility ■ Direct delivery to pharmacies: Bypass traditional wholesalers

Source: Arthur D. Little

strengthen based on access to selected and individual data gained in the process, which would allow for further development.

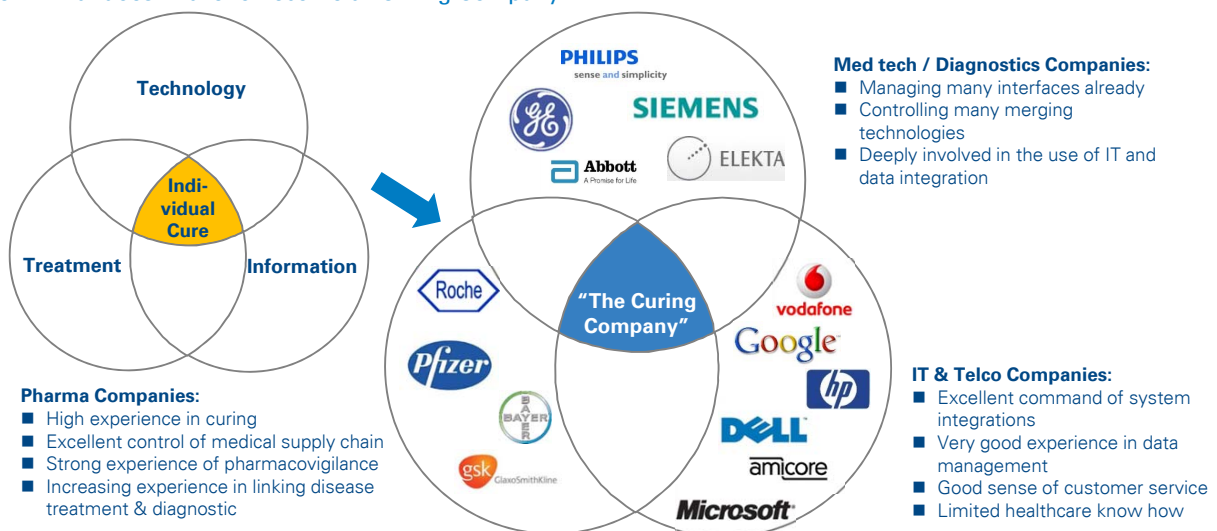
What is more, the Curing Company concept can help the pharmaceutical and medical industry in addressing many of the typical challenges they currently face (see Figure 3), be it in terms of supporting the refocus on its core science, its extending focus on patient centricity, or the need to integrate new technologies.

Clearly, the major hurdle to be overcome is the vast scale of competencies required to be a true "closed loop" Curing Company. As the individualised cure sits at the crossroad of technology (med tech and diagnostics), treatment (pharma) and information (IT & telecoms), hardly any company can claim to possess all the necessary expertise to do the job. Medical technology and diagnostics players such as Philips, GE or Siemens appear to currently hold the best position to assume a leading role as a Curing Company, as they already manage many interfaces, control merging and emerging technologies, and are deeply involved in the use of IT

and data integration. Nevertheless, even they will need the thorough expertise of pharma and IT/telecom partners to fully address the personalised medicine challenge. Recently, several partnerships in this respect have seen the light of day, such as the earlier mentioned GE/Intel JV, but also IBM & Aetna's cloud computing for on-demand clinical decision support (see Figure 4).

The challenge is to manage the bridge between the traditional (bio-)pharma companies and the newcomers. This delicate balance will require a cultural shift within the traditional pharma industries who will need to establish new partnerships to access the Curing Company model, slowly integrating into the full picture. There is no "perfect recipe" for this partnership, as every situation will be different (and, may we say, will require a personalised approach). Nevertheless, it is clear that mergers or partnerships where the leading parties bring in the required technology, and the "traditional" pharma players offer the (pharmaceutical) treatment support and know-how, have the best chances of success in harnessing the best of both worlds.

Figure 4. What does it take to become a "Curing Company"?



Source: Arthur D. Little

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