

Innovation in the healthcare space

How new technologies are driving fundamental changes in the pharmaceutical business model

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The global pharmaceutical market is expected to reach a size of 1 trillion USD by 2014¹, with continued high profitability between 28% - 46% EBITDA². For many years the market has been driven by innovation, and scientific advancements have made drugs ever more targeted. With the new generation of diagnostics technology, those few individuals that will benefit most from a given therapy can now be selected from large populations. This means that after many decades of running a successful “blockbuster” model for new drugs, the business model for companies has evolved much more towards Specialty Pharma, targeting diseases with a low incidence and a more limited number of patients with a high medical need. In this environment, small and mid-sized pharmaceuticals companies are now in a stronger position to efficiently commercialize their drugs towards small, focused, target groups. In order to maintain their innovation leadership in the Specialty Pharma arena, established large companies have therefore had to buy access to high performance diagnostics and targeted therapies.

In parallel, advancements in IT have proceeded apace and are about to have a revolutionary impact on pharmaceutical business models. Driven by the Internet, mobile devices and cloud technologies, along with increased processing speed and capacity, complex individual diagnostic data and therapeutic patient records can now be analyzed against a background of massive amounts of population data, with the results then made available to almost anyone, at any time, everywhere in the world.

The business model of the pharmaceutical industry is changing fast: The era of blockbuster medications with big margins is over. Instead, patient-centric medication is the way forward. While the industry is still grappling with these facts competition from another side is entering the field: tech companies are currently investing heavily to reap large profits from e-health concepts. In the article the authors discuss how pharma companies can react in order to survive in this new environment.



Illustration by Sylvia Neuner

¹The IMS institute, the global use of medicine, outlook 2017

²Company reports of Global Top 10 Pharma companies

Like many other industries, this digital transformation is causing significant disruption to established value chains and business models, with new players emerging from outside the traditional healthcare sector. In this article we examine how leading players have responded to recent trends in the pharma industry, and suggest what pharma companies need to do next in order to win in the new digitalized environment.

Transformation of the business model towards Specialty Pharma

The pharma business model and key success factors have significantly changed over the last decade. For example, the share of Biologics from the total number of "new molecular entities" has risen from 25% 20 years ago, to nearly 75% in 2010, as shown in Table 1.

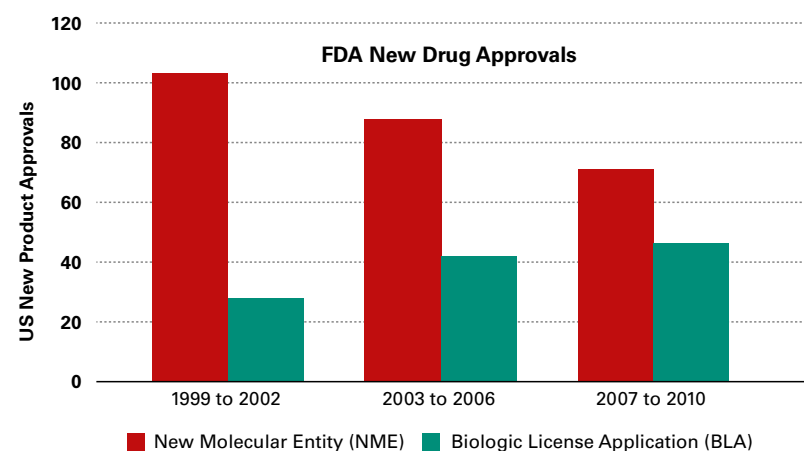
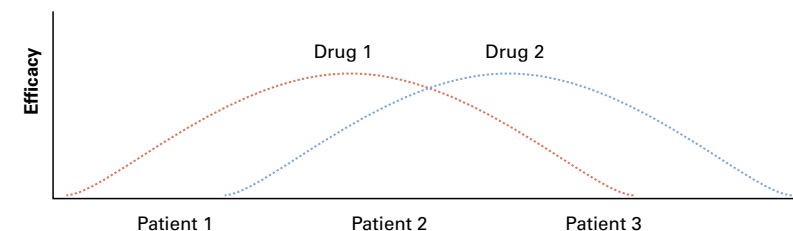


Table 1
The declining number of traditional therapeutics vs. growing number of Biologics

Source: Centers for Medicare & Medicaid Services; EvaluatePharma

At the same time, better diagnostics have made therapies more focused. This has marked the transition from the Blockbuster model (which was worth double digit billion USD in peak sales) to the Specialty Pharma model. Whilst new drugs are still able to reach the billion US Dollar landmark in annual sales, this is now based on the price premiums that companies can achieve based on medical evidence and higher efficacy, driven by a better selection of patient populations. Table 2 illustrates the difference between the two

Traditional Pharmaceutical Model:



Specialty Model:

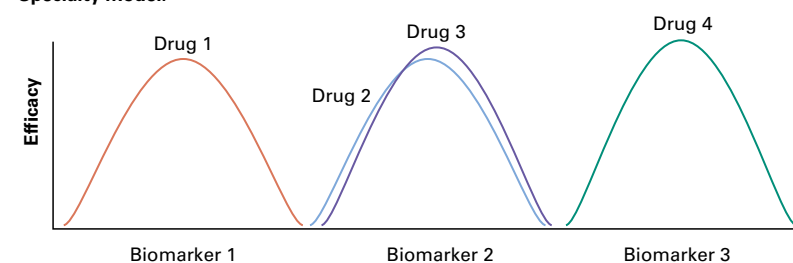


Table 2
Evolution of therapies: traditional vs. Specialty Pharma model

Source: Arthur D. Little

models: whereas in the blockbuster era one molecule was directed to a larger group of patients, the Specialty Pharma model is much more specific.

This trend towards a more personalized type of medicine has been driven significantly by companies like Roche, which were able to select and acquire the winning technology platforms. This means that Roche today is a market leader in combining diagnostics with therapies. The company has shown the ability to acquire the necessary capabilities in diagnostics and proteomics early in the process, and thus has obtained a leadership position which is ahead of most of its competitors.

Roche – market leader in the combination of diagnostics and therapies³

Roche was founded on October 1st, 1896. With a strong focus on thyroid drugs and vitamins, the company grew and developed a series of breakthrough innovations such as the discovery of the tranquilizing effect of benzodiazepine, a number of highly active formulations against acne and chemotherapies against cancer. Roche also acquired the patents for the polymerase chain reaction, a key technology in the early days of genetics.

The history of Roche is also a series of smart mergers. Through the acquisition of Boehringer Mannheim in 1997, the company gained access to diagnostics and the first biotech projects, and through the Genentech deal, which was fully concluded in 2009, clear leadership in biologics and personalized medicine was secured for decades to come. The company is aware that there are breakthrough innovations elsewhere, and tries to address this with an open culture. Roche CEO Severin Schwan said in Prism 2/2013: “I always tell my people that probably 99% of all discoveries happen outside of Roche, so we need to stay open and bring in external expertise to the company.”

The rapid growth of Specialty Pharma is creating an inflection point across the entire healthcare landscape. Substantial differences between Specialty and traditional pharmaceuticals – not only structurally and chemically, but often in terms of distribution, marketing, and regulation – are challenging the health care ecosystem. The discovery, development, manufacturing, delivery, and sales of specialty pharmaceuticals require new and advanced tools, techniques, and expertise. The growth of Specialty Pharma is therefore not only driving significant change across the entire value chain, but also has important implications in terms of value creation market opportunities for traditional players and new entrants alike.

Whereas long-term established players like Roche drove the change mainly by the combination of diagnostics and therapies, rising new companies, such as Shire, started to focus on rare diseases with a high medical need. In fact, the success of Shire was built on a series of M&A transactions and the establishment of a virtual value chain which enabled the company to operate with a minimum of fixed assets, targeting limited patient numbers with specialized therapies.

³Roche.com, milestones, March 2014

Shire – mastering business development and regional expansion in Specialty Pharma⁴

Shire’s future growth strategy reinforces its focus on the Specialty area, where innovation still enables companies to differentiate and to drive value. The focus will be on developing and providing innovative specialty pharmaceuticals for niche and orphan indications to meet significant unmet patient needs.

Shire’s current product portfolio now contains specialty pharmaceuticals in the area of attention deficit hyperactivity disorder (ADHD), gastrointestinal treatments, and renal disease. Leading orphan drugs and highly specialized treatments in the area of lysosomal storage disorders for Fabry disease and Hunter syndrome, as well as hereditary angioedema, complete the portfolio. They all have three aspects in common: they target extremely rare diseases with an incidence of one patient in a population of 10 -150,000 people, address conditions with a high medical need, and are able to charge between 150 - 400,000 USD per patient for annual treatment costs.

Throughout its 30 year history, Shire identified, acquired and successfully integrated a number of targets and product portfolios. Its capability to systematically screen the option space of medium to late stage development compounds and portfolios is a competence that is ahead of the industry.

Other examples of traditional pharma companies moving into Specialty Pharma include Sanofi^{5, 6}, who successfully acquired Genzyme, a biotech leader in the treatment of orphan diseases. By acquiring Genzyme, Sanofi both reinforced its biologics portfolio and initiated a new culture of specialty biopharma. The deal also strengthened Sanofi’s competitive position in the US.

⁴Shire.com (investor news, 2013 Q3 and Q4 earnings presentations, results 2013, press release 13 February 2014)

⁵Sanofi’s annual report 2010 (February 09, 2011), Announcement of the acquisition of Genzyme (February 16, 2011), annual report 2013 and investor presentation (February 06, 2014), interviews

⁶Wall Street Journal, Feb. 17, 2011, “Sanofi Wins Long-Sought Biotech Deal”; Bloomberg

In summary, the value chain of pharma companies has been transformed by a number of drivers from science and technology, fuelled by research-driven, small and mid-sized companies, and university spin-offs. Companies have largely adapted towards this and most of the big players have managed to buy and build their way into the new model.

The transformation towards Digital Pharma

Today, IT advancements are starting to further transform the pharmaceutical value chain. The digitalization of large parts of the world's population is giving people access to health-relevant information and services, which have only just begun to be developed. For example, "Telehealth" and "Mobile Health" (m-Health) applications have the potential to greatly improve prevention and early therapy success. Running apps, heart rate measurements and glucose monitoring applications are moving beyond the exploratory

stage and will soon be integrated into existing care pathways - or even define their own new pathways with the patient at the center. Table 3 shows the different categories of m-Health applications that can be used by consumers, as well as health professionals and administrators, depending on the actual health status of the individual person.

Obesity, one of the most significant burdens on healthcare in developed countries, can now be approached through these new measures. Patients will therefore evolve towards being "consumers" of healthcare services.

If applied in a smart way, these health lifestyle solutions will have an enormous potential to tackle chronic mass diseases such as diabetes, cardiovascular disease, back pain, and depression. The convergence of medical advancements and IT is a clear trend in the development of clinical practice and has been described by authors such as Eric Topol in his book "The creative destruction of medicine"⁷. Based on a recent Arthur D. Little survey amongst senior pharma executives⁸, the industry clearly sees the significance of the impact digital technologies will have on its business model, but is today still lacking strategies to tackle it. Companies stumble over the fact that becoming leaders in this area requires significant upfront investment and a business case which does not deliver the kind of ROI the pharma industry and its shareholders are used to. It requires a high initial investment, and provides a disruptive business model with risky benefits.

One of the new players approaching healthcare from the IT, media, electronics and mobility angle is Google. With its recently launched CALICO (California Life Company) initiative, Google is putting pressure on traditional pharma companies to adapt their business model to the digital world of the future.

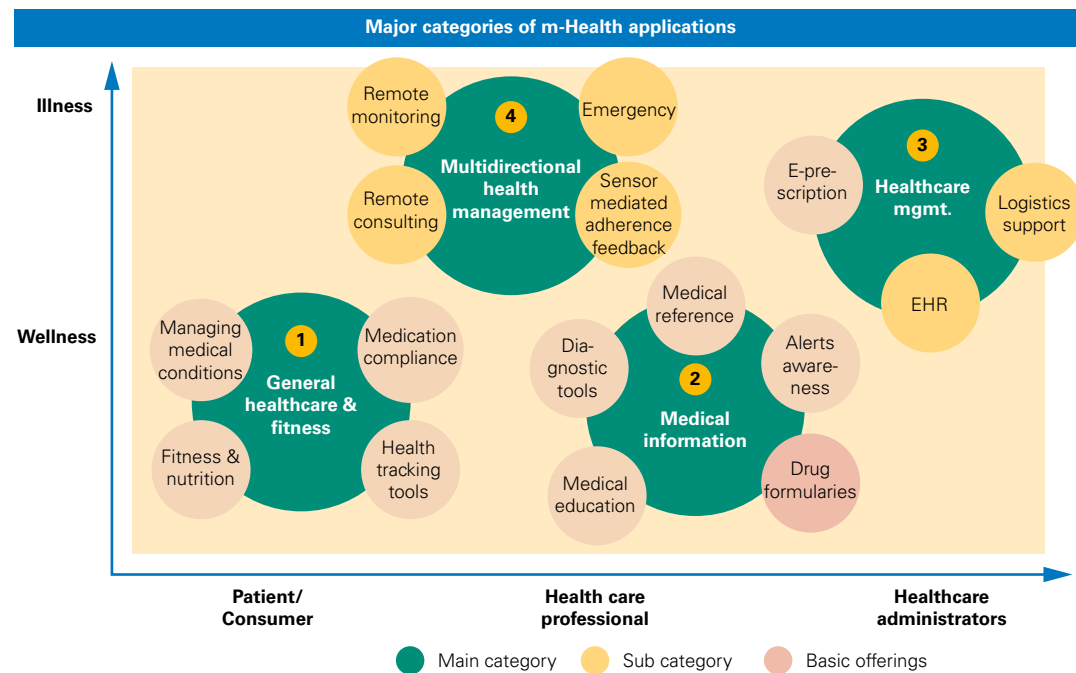


Table 3 Major categories of m-Health applications

Source: Arthur D. Little

⁷ Eric Topol: The creative destruction of medicine, January 2012, Basic Books (Perseus Book Group)

⁸ Study: impact of digital health on Pharmaceutical industry, Arthur D. Little, January 2014

Google's Moonshot program in Healthcare^{9, 10, 11}

Google's approach could not be any more different: whereas pharma companies take 10-15 years to quietly develop new molecular entities (NMEs) in areas such as cancer, Google announced in September 2013 with its Moonshot thinking that it wanted to "solve the problem of death."

Google today has a total turnover of 60bn USD, 48,000 employees worldwide and an operating profit level of 14bn USD in 2013. Pharma giant and market leader Pfizer is generating about the same level of turnover and profits with just under double as many employees (92,000 in 2012). Google's profits are driven by its core business Google Search and online advertising. In September 2013 Google launched a healthcare company to attack some of the most difficult scientific problems in diseases related to ageing, marking the biggest step yet beyond its core internet business.

Larry Page, chief executive, unveiled the venture, called Calico, with a characteristically ambitious and vague claim that "with some longer term, Moonshot thinking around healthcare and biotechnology, I believe we can improve millions of lives."

The new venture is to be headed by Art Levinson, the former chairman of biotech company Genentech, which was bought by Roche in 2009. Mr. Levinson brings along a team of researchers from Roche and his personal network.

The move to Digital Pharma implies new business models and players, leading to a different market structure which consists of:

- Established traditional large pharma players
- Specialty Pharma players
- New game changing market entrants.

Companies like Roche are leading through the combination of diagnostics and therapies, Specialty Pharma players such as Shire market their drug product innovations to a targeted group of patients, and the new market entrants such as Google aim to mobilize consumers to directly access healthcare solutions.

⁹Time, 30. September 2013: Calico: Google's New Project to Solve Death

¹⁰Capital, March 2013

¹¹Die Zeit, January 2014

All players are driven by innovation. The traditional pharma value chain is going to change for these reasons:

- R&D needs to adapt to combine drugs and devices, diagnostics and IT.
- Manufacturing can benefit from the Internet of Things and inventions such as 3D printing.
- Market access will be dependent on evaluation of real life data.
- Marketing will focus more on consumers, less on prescribers, and will address a solution to a problem rather than focus on a physical product only.
- Sales will be increasingly directly to patients, enabled by online channels.

This digital transformation affects each part of the value chain and thus needs to be managed comprehensively. It has the potential to be truly disruptive¹², because it targets a much wider range of customers, with a simple but modern approach of bringing healthcare gradually to consumers instead of having them travel to wherever healthcare is provided.

How companies can respond to the Digital Pharma challenge

Pharma companies generally suffer from possessing the biggest barrier towards innovation and change – a sizeable and profitable existing business. Decision makers are afraid of margin dilution, whatever new business they introduce. However, in order to maintain their market position over the long term, pharma companies need to embrace digital transformation. They have a range of options with which to respond. They can drive change from within, spin-off their new digital business arms, or access essential new capabilities through JVs, partnerships or mergers and acquisitions.

¹²<http://www.claytonchristensen.com/key-concepts/>

In order to succeed in this environment, we have identified five key ingredients:

1. Deep knowledge of disease patterns and therapeutic pathways
2. Regulatory competence to ensure applications are safe and well accepted by authorities
3. Cutting edge biochemical technologies in the medical therapy space
4. Offerings that directly attract consumers and patients
5. Competence in digital and media technology to ensure smooth application in practice.

Whereas the first two of these are core competencies of traditional pharma companies, innovative small and mid-sized biotech companies own the innovation space for the third.

Attractive, workable solutions for consumers are critical. Offerings must gain acceptance, or even better, create a strong desire to use them in consumers and health professionals. We set out some principles of winning Digital Health offerings in Table 4:

It is obvious that these capabilities are very much owned by today's digital media companies. Established players will therefore need to acquire this new set of tools to successfully play in the new world of pharma. They have to become familiar with direct patient/consumer interactions and gain access to digital technologies. In doing so, they can choose from a number of different options in order to prepare their business model for the digital age:

- **1 Defend:** Defend their place in the ecosystem by pushing for drug innovation, quality surveillance and the involvement of the medical community which they are familiar with.
- **2 Partner:** Partner with emerging players from the IT/Telecom/Internet business space to access their technical capabilities related to IT, Telecommunications and their customer base.

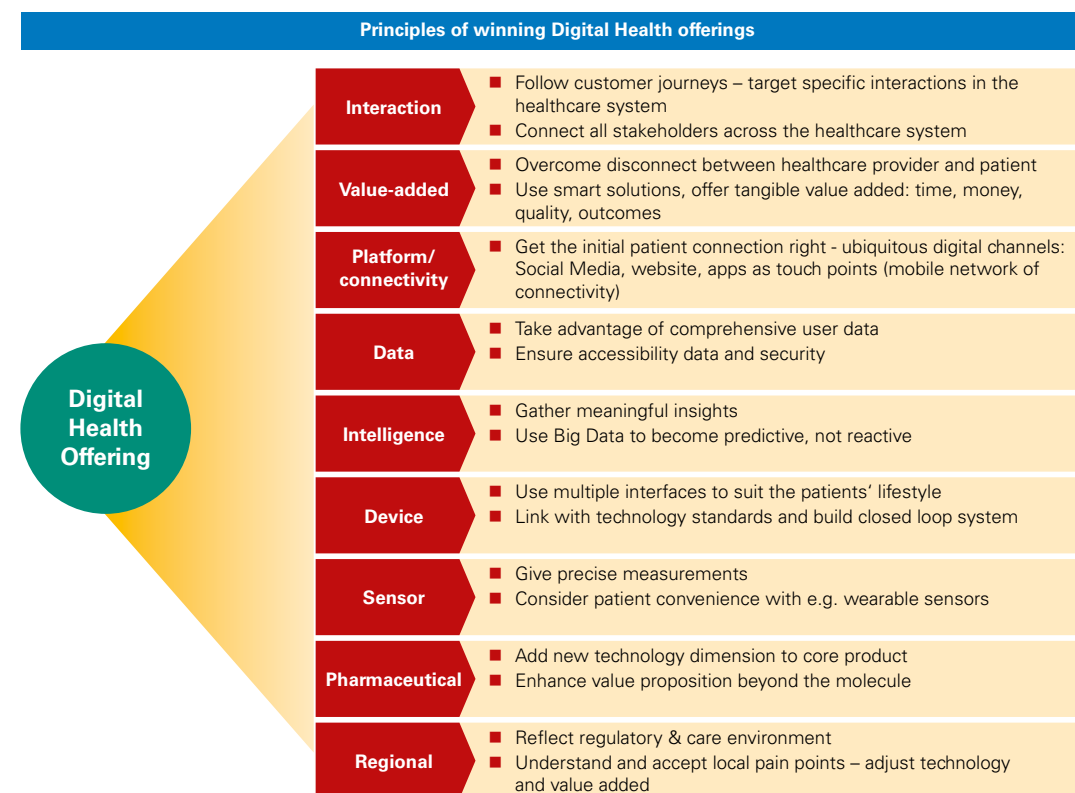


Table 4 Principles of winning Digital Health solutions

Source: Arthur D. Little

- **3 Transform:** Transform their business to become digital experts and connect the dots between IT and medicine to become the first choice for caregivers, not only as a drug supplier, but also as a provider of therapeutic solutions.

The Specialty Pharma players need to extend their commercial platforms, and acquire the tools of the new players, while new entrants will have to acquire the medical and regulatory know-how to deal with established care structures. They need to further expand their value chain to find profitable commercial models in different geographies and develop secure and efficient distribution chains. Those who are focused on orphan indications have the opportunity to consolidate their knowledge about how patients benefit from treatment with their drugs. They will then be able to utilize

this knowledge to create digital offerings which support patients in order to further improve their quality of life. These may include nutritional information and online shopping opportunities, guidance about how to deal with disease specific complications, maps with centers of excellence near their location, and opportunities to engage in clinical trials.

One option for established players to overcome the barriers of past success is to spin-off new ventures to give them the space and freedom to develop to a point where they can begin to disrupt the pharma model. Although losing some meaningful synergies, for many of the larger pharma companies this might be the only solution to ensure a sustainable development of innovative digital approaches.

The new emerging players from the IT/Telecom/ Internet business side have by nature different shortcomings to established players. Firstly, they need to acquire medical knowledge. Their rule-breaking attitudes will only prevail once their initiatives are backed by regulators such as the FDA, and at least parts of the medical community and payer organizations. Each of these stakeholders can only be convinced through the creation of medical evidence, a discipline which as of today is still the key domain of established players.

Insights for the executive

Recent developments in the healthcare industry provide some useful insights that are also relevant for other sectors. For example:

- 1) Business models even in profitable industry segments with high barriers to entry are subject to change and disruption.
- 2) Change is often driven by new technologies which are not necessarily invented in the same industry.
- 3) Business model transformation is often accompanied by the rise of new players who are better adapted to the new environment than established players and have less to lose.
- 4) Established players need to decide their response strategy: either adopt a leadership position, or buy into it at a later stage. Doing nothing is not an option as disruption gathers pace.

Many established players aim for business sustainability, based on the interests of their shareholders and stakeholders such as customers, employees, governments and societies. A key pillar to ensure sustainability is the imagination to draft a vision of the mid- and long-term future of the business. Pursuit of this vision must be fuelled by creativity and entrepreneurial power to transform the company's capabilities to succeed.

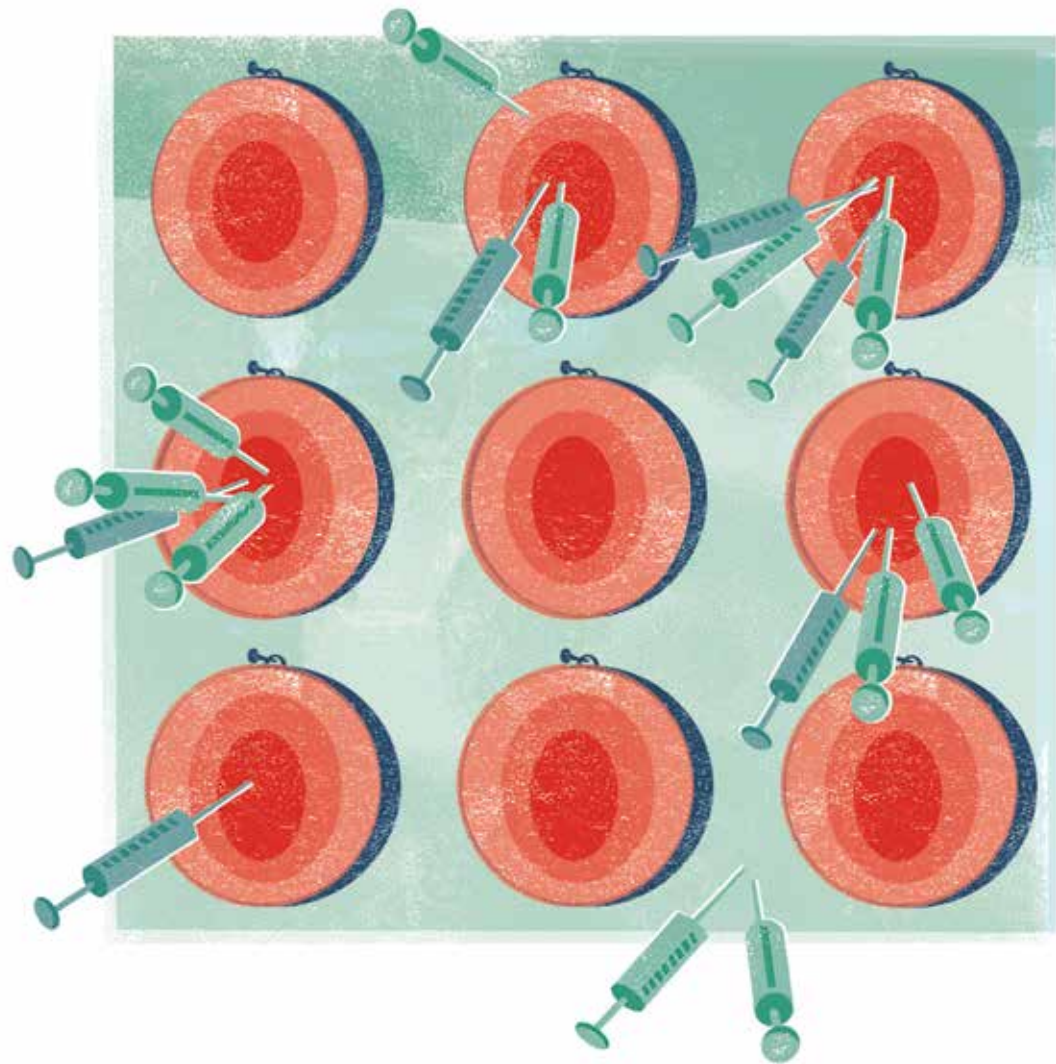


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