

EVOLUTION OR REVOLUTION

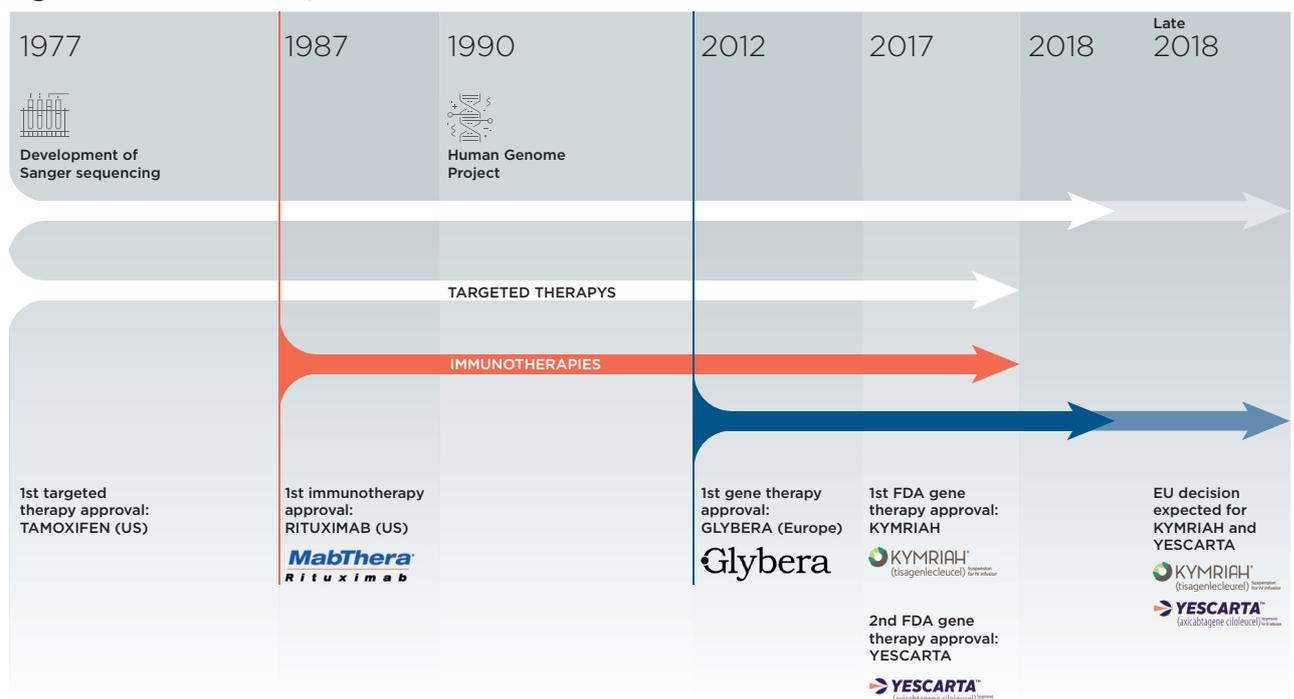
By Laura Savi

The first whole human genome sequence was completed in 2003, and in the intervening years its influence has reshaped the clinical landscape and ushered in a new era of personalized medicine. Yet the healthcare sector faces a challenging future, wherein stakeholders must achieve a delicate balance between the traditional and the new to meet financial challenges and innovate in care delivery. Is it a case of evolution or revolution?

Genome analysis and sequencing effectively cut through uncertainties associated with companion diagnostics in the early 2000s, enabling instead the introduction of targeted therapies and immunotherapy which, in turn, led to innovative treatments for cancer and other serious conditions.

Moreover, the analysis of gene expression pattern has significantly advanced personalized neoantigen therapy, enabling patients' own immune systems to fight cancer. Only last year, the FDA approved a new cancer therapy that uses genetically engineered immune cells to treat an often-lethal type of blood and bone marrow cancer that affects children and young adults (**Figure 1**).

Figure 1. Launch timeline; PM evolution



Managing financial challenges and affordability

While genomics has clearly been, and will continue to be, a catalyst for innovation in treatments and personalized medicine, its emergence has posed financial sustainability challenges for healthcare systems across different geographies. Pressure on healthcare

budgets has been steadily increasing over the last fifteen years, giving rise to new managed entry agreements and innovative contracting solutions. Such initiatives have taken centre stage in HTA/ Pricing and reimbursement negotiations in many markets, and the adoption of performance-based schemes in oncology, while not universal, has grown significantly in the US and Europe, notably in Italy, the UK, the Netherlands and Sweden **(see Figure 2)**.

Figure 2. Geographic concentration of publicly available innovative contracts

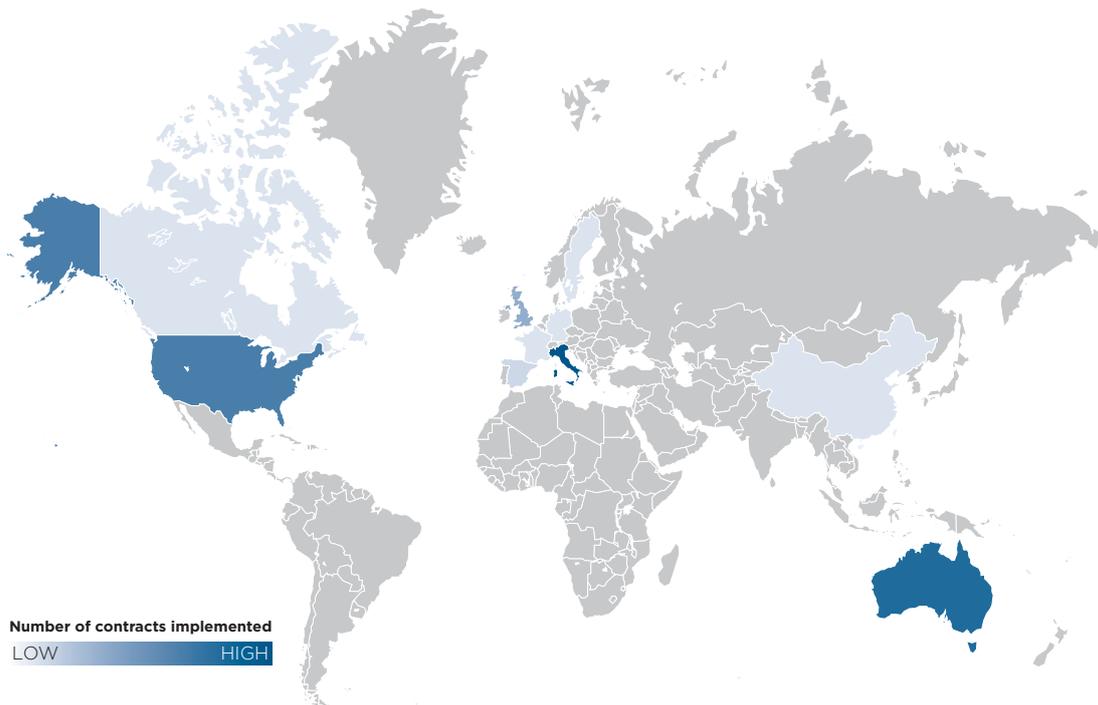


Chart 1. Number of performance-based risk-sharing arrangements by year

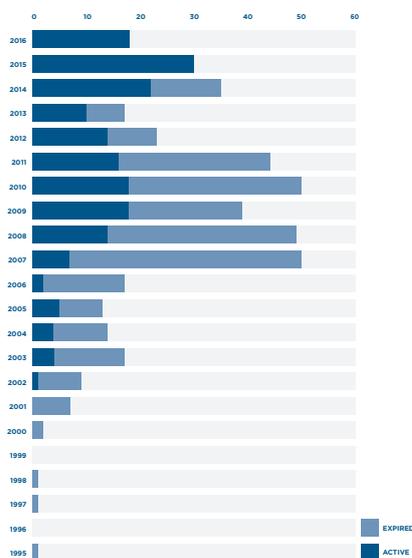
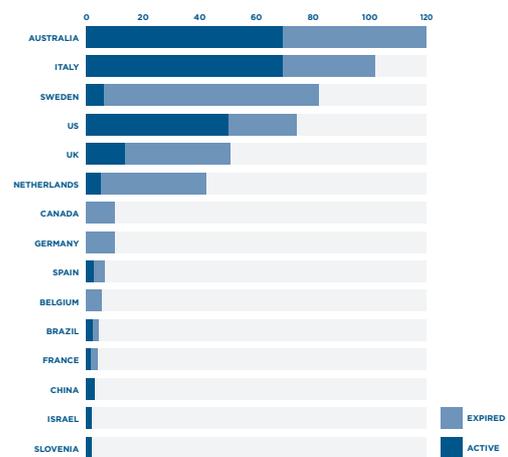


Chart 2. Number of performance-based risk-sharing arrangements by country



"Performance-Based Risk-Sharing Agreements: An Updated International Review" by Josh J. Carlson et al., PharmacoEconomics (2017) 35: 1063-1072
<https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/innovative-pharma-contracts-when-do-value-based-arrangements-work>
https://depts.washington.edu/pbrs/PBRS_slides.pdf
<https://link.springer.com/article/10.1007/s41669-017-0044-1>
<https://link.springer.com/article/10.1007%2Fs40258-014-0093-x>

Affordability, value for money and innovative funding solutions will continue to be priorities for the evolving life sciences' market. It's a conundrum: more advanced treatments may be possible, but are they financially viable and accessible in a mainstream healthcare model? Cancer treatments provide a useful example here. While tumour heterogeneity and drug resistance are very common issues, the evolution of combination therapies by life science agencies offers the potential to overcome underlying drug resistance and formulate more effective treatments. On the financial downside, however, the cost is the sum of two highly priced therapies.

In dynamic and evolving healthcare markets, the ability of stakeholders to adapt quickly and appropriately is critical to success. Consider, for instance, how the falling cost of genome sequencing is impacting traditional pharmaceutical companies. Since its inception at the turn of the millennium the cost of sequencing has plummeted from millions of dollars to just \$10,000 by 2010 and it's now

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predicted that genomes may soon be essentially free. For companies, this may require new strategies; perhaps subsidizing genome testing as the movement toward personalised care and prevention evolves. Greater access to individuals' genomic data will certainly enable companies to focus more on individualized value propositions, that is to say matching the right drug, (and dose) with the right patient at the right time. Certainly, companies are already developing more sophisticated, patient-centred, diagnostic techniques, including proteomics, (i.e. the measurement and analysis of the thousands of

proteins from the blood that can be measured and potentially lead to early disease detection) and point-of-care devices that measure blood-based proteomes.

While financial sustainability is critical, the future evolution of healthcare and life sciences markets will also be shaped by disruptive change and innovation. And it is probable that such forces will impact not just the way treatments are financed, but the way in which healthcare systems themselves are structured and managed.

Taking gene and cell therapies as an example, it is likely that future commercialization challenges will extend beyond cost and payment models, influencing:

- Complex administration protocols and clinical care requirements
- The evolution of highly specialised resources with constrained medical capacity in order to deliver therapies and manage their side-effects post administration
- The development of further medical education to ensure high-quality of delivery
- Treatment delivery models: concentration of treatment in a potentially smaller universe of centres may require a more flexible approach than found in traditional biopharma field sales models.

Furthermore, to add to these challenges, uncertainty about the speed of change makes it increasingly difficult for healthcare stakeholders to adjust to it.

Reinventing care delivery through innovation and advanced technology

If developing better, more affordable treatments is critical to the future of healthcare, so too are the ways in which care is delivered. Reinventing care delivery is all about using resources

efficiently while exploiting opportunities offered by new technologies and innovative approaches. The convergence of advanced medical research, super fast computers, a rapidly-developing mobile infrastructure and broadband internet technologies underpins much innovation.

Artificial Intelligence (AI), which is playing an increasingly important role in the Life Science world is a prime example. AI has the potential to take genomic profiling, personalized medicine, and medical imaging to the next level. It also promises to streamline analysis and R&D - analysing large data sets efficiently to produce the rich insights needed to drive advanced modelling, better extrapolation, bolder hypothesis and more targeted research.

Likewise, the digitization of medicines are reshaping the delivery landscape. Digital solutions, such as real-time glucose monitoring and mobile drug reminder/compliance programs, not only have the ability to enhance patients' care, but also to lower costs (through enhanced compliance and by avoiding episodes of hypoglycaemia and associated high treatment costs). The continual shift from paper to electronic patient records and from analogue to digital medical solutions will:

1. Enhance the speed, accuracy and cost-efficiency of diagnostics
2. Drive decision support for applying increasingly available evidence-based data sets
3. Enhance the fit between therapy and individual patient needs.

And in a world where big is often beautiful, medical technology is becoming ever smaller, more mobile and more capable of making real differences to patients' quality of life. Just as the advent of biotechnology helped the pharmaceutical industry to achieve some of its biggest breakthroughs in the last few decades, so the emergent nanotechnology could usher in a new, but just as profound era. The potential

is surely huge, with the future possibly giving rise to nano-scale structures across a range of areas, from artificial blood cells to nano robots that can autonomously perform diagnostic and therapeutic functions.

So Evolution or a Revolution?

The answer is both, that is to say a hybrid that combines the best of the existing world with the potential of the new. Clearly, the pharmaceutical industry will still need cost-effectiveness models, pricing and contracting solutions and value communication tools to navigate successfully as the market evolves. Critically, however, these need to be augmented by a broader set of skills, capabilities and relationships that meet the changing needs of stakeholders in the decades to come. It is obviously more difficult to prepare for the latter, which is why companies' willingness to invest early in key areas/ technologies and transition to flexible models will decide how well they adapt to these changing environments. Ultimately, a successful future is one in which healthcare systems are best-placed to battle the ever-increasing challenges of reducing costs, increasing access and improving care.

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