

Can Europe deliver the promise of advanced therapies?

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Europe has made remarkable scientific progress in advanced therapies. The next challenge is ensuring healthcare systems can translate these breakthroughs into timely, affordable and equitable patient access at scale

Few areas of medicine have evolved as rapidly as advanced therapies. Gene and cell therapies are transforming the treatment of cancer, inherited disorders and other life-threatening diseases. Rather than simply managing symptoms, many address the underlying cause of disease and, in some cases, offer the possibility of long-term remission – or even cure. CAR-T cell therapy is one of the most striking examples of this transformation.

Pioneering work by Professor Carl June at the University of Pennsylvania and other researchers demonstrated that genetically engineered immune cells could eliminate cancer in patients with otherwise incurable blood malignancies. More than a decade after the first patients were treated, long-term follow-up continues to demonstrate durable remissions and long-lasting clinical benefit.⁽¹⁾

Yet despite these achievements, access remains limited. In Europe, only around 18% of eligible patients receive CAR-T therapy.⁽²⁾ Significant barriers remain around manufacturing capacity, referral pathways, reimbursement and treatment infrastructure. For many patients, the challenge is no longer whether these therapies work, but whether they can access them.

This highlights a growing innovation-to- access gap: scientific breakthroughs alone do not improve outcomes unless healthcare systems can deliver them to patients.

Why health-system readiness matters

Advanced therapies have the potential to transform lives, reduce long-term disease burden and, in some cases, replace years of chronic treatment with a single intervention. At the same time, they challenge today's healthcare systems.

Manufacturing remains complex, treatment is expensive, and demand is expected to increase as more therapies become available. To benefit more patients, innovation must reduce manufacturing time and costs and make treatment practical for routine healthcare.

This makes health-system readiness – from manufacturing and infrastructure to clinical delivery – a priority for the next phase of advanced therapies.

Unlike conventional medicines manufactured in large batches, every CAR-T therapy is individually produced from a patient's own cells. Production is highly specialised, frequently requiring four to six weeks from cell collection to reinfusion, and treatment takes place in specialised centres. These factors limit capacity, contribute to high costs and make large-scale implementation challenging.

Automation, digital technologies, closed manufacturing systems and point-of-care manufacturing have the potential to shorten production timelines, increase capacity and reduce costs.

These advances are essential if advanced therapies are to reach many more patients.

“Scientific discovery created the opportunity. Europe's next challenge is building healthcare systems capable of delivering advanced therapies at scale.”

But manufacturing innovation alone is not enough. European stakeholder analyses show that barriers extend well beyond manufacturing. Regulation, reimbursement, health technology assessment, hospital capacity, workforce, clinical organisation and long-term investment all influence whether patients ultimately receive these therapies.⁽³⁾

The challenge is no longer only developing breakthrough therapies, but ensuring healthcare systems can deliver them.

Building the systems to scale advanced therapies

Point-of-care manufacturing illustrates how technological innovation and health-system transformation need to develop together. Producing therapies at or close to the treating hospital has the potential to shorten treatment timelines, reduce logistics and improve efficiency.

Bringing manufacturing closer to patients also requires healthcare systems to evolve. Hospitals need new clinical pathways. Laboratories, pharmacies and clinical teams must work together in new ways. Digital systems must support secure information exchange, while regulators, healthcare providers and industry need practical solutions that make innovation safe, efficient and sustainable.

Scientific innovation must therefore be matched by healthcare innovation.

Europe has a unique opportunity to lead this next phase. European Framework Programmes, Horizon Europe and the Innovative Health Initiative (IHI) have demonstrated how collaboration between academia, hospitals, industry, regulators and patient organisations can accelerate scientific progress.

The next challenge is applying the same spirit of collaboration to patient access. Europe has invested heavily in developing advanced therapies. It must now ensure healthcare

systems can adopt these innovations efficiently, affordably and at scale.

This ambition aligns with the European Commission's Life Sciences Strategy, which identifies biotechnology and advanced therapies as strategic priorities for Europe's future competitiveness.⁽⁴⁾

From innovation to implementation

European public-private initiatives can help turn this vision into practice. The IHI-funded EASYGEN consortium is one example.

Alongside developing manufacturing approaches that aim to shorten production timelines, reduce costs and support decentralised delivery of CAR-T and gene-modified immune cell therapies, the consortium addresses practical implementation challenges, including clinical workflows, regulatory science, digital integration and health-economic evaluation.⁽⁵⁾

The objective is straightforward: innovation should not only create better therapies – it should enable many more patients to receive them.

Scientific discovery has changed what medicine can achieve. Manufacturing innovation is making advanced therapies faster, simpler and more affordable. Ultimately, Europe's success will not be measured by the number of scientific breakthroughs it generates, but by its ability to translate them into timely and equitable patient access.

The next phase of innovation is therefore not only scientific, but also organisational, regulatory and economic. Europe's ability to turn scientific leadership into healthcare-system readiness and patient access will help determine both future patient outcomes and its global competitiveness in life sciences.

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