Advanced therapies: a strategic pillar for European autonomy in biotechnology and health

- **Early Health Technology Assessment (HTA) prevents investments in developments that will not deliver real value, while allowing patients faster access to truly innovative treatments.**

- **The upcoming Biotech Act and the European Pharmaceutical Strategy are crucial for the development of advanced therapies in Europe, as they aim to create a more agile and predictable regulatory framework that facilitates innovation, clinical research, and industrial production of these treatments.**

- **Experts point out that effective implementation of artificial intelligence in hospital settings requires proper data infrastructure, interoperability strategies, and clear regulatory frameworks to accelerate clinical impact.**

Barcelona, October 8, 2025. – **Advanced therapies** are emerging as a strategic pillar for **European autonomy in biotechnology and health**, enabling the development, manufacture, and distribution of high-value innovative treatments without relying exclusively on other global markets. This emerging field in Spain, together with the challenges of implementing artificial intelligence and new proactive approaches in health technology assessment (HTA), was the focus of the BIOSPAIN 2025 International Biotechnology Meeting, held from October 7–9 at Fira de Barcelona – Montjuïc, organized by the **AseBio** and Biocat, in collaboration with the Generalitat de Catalunya and the Barcelona City Council.

Advanced therapies are innovative treatments using genes, cells, or tissues to treat or even cure diseases for which few alternatives currently exist, such as certain cancers, rare or degenerative diseases. According to **Elena Erroba, Chief Commercial Officer (CCO) of 3PBIOVIAN**, Spain is establishing itself as a reference in this field thanks to its network of research centers, hospitals, and active clinical trials. Furthermore, she highlighted that the upcoming European Biotech Act aims to provide Europe with a stable and competitive framework capable of placing biotechnology and life sciences at the center of industrial, health, and economic strategies for the coming years.

As Elena Erroba emphasized, the Biotech Act, together with the European Pharmaceutical Strategy, is key for the development of advanced therapies in Europe, "as they seek to create a more agile and predictable regulatory framework that facilitates innovation, clinical research, and industrial production of these treatments." Additionally, according to the 3PBIOVIAN CCO, they strengthen collaboration between countries and access to key technologies, "reducing dependence on third parties outside Europe."

High-cost facilities

Although Spain is advancing strongly in the field of advanced therapies, large-scale integration into the healthcare system and industry still presents significant challenges. As Elena Erroba pointed out, the first major challenge is industrial scale-up and manufacturing capacity, "due to the high cost of high-tech facilities, specialized

personnel, and strict controls." From a regulatory perspective, experts have noted that processes still need to be faster and more flexible to avoid delays in bringing innovations to patients. Moreover, as Erroba highlighted, "the training and retention of highly qualified multidisciplinary teams is a critical aspect."

The adoption of more proactive approaches in health technology assessment (HTA) in Spain also faces challenges, such as coordination between autonomous communities, although the country is in a consolidated development phase. According to **Fernando Fraga Pedroche, Knowledge Transfer Officer at the Knowledge Transfer Office of the Carlos III Health Institute (ISCIII)**, "we are in an intermediate position in Europe: we are not leaders like the Nordic countries or the Netherlands, but we are not lagging behind either."

According to the expert, HTA is a comprehensive analysis that determines whether a new medical technology provides real value to the healthcare system. "We don't just look at whether it works clinically; we evaluate safety, effectiveness compared with existing alternatives, economic impact, and ethical and organizational implications," detailed Fernando Fraga Pedroche. Traditionally, this evaluation was reactive: "We waited for the technology to receive marketing authorization and only then evaluated whether to fund it." The problem with this approach, the expert warned, "is that enormous resources have already been invested, and if we detect problems, it is too late to correct them."

A more proactive approach allows for better planning and early identification of technologies with the highest potential impact. For patients, as Fraga Pedroche noted, this means faster access to truly innovative treatments. "By resolving uncertainties during development, subsequent evaluation and funding processes are more agile," he argued.

Artificial intelligence in hospitals: an ongoing challenge

Advances in artificial intelligence (AI) have already transformed sectors such as healthcare by offering personalized treatments through the analysis of genomic and clinical data to predict the therapy that will work best for each patient. In preventive medicine, AI identifies risk patterns before diseases develop.

Fernando Fraga Pedroche emphasized that Spain is currently growing in the implementation of AI in hospital environments, but unevenly. "We have pioneering centers like Hospital 12 de Octubre and Hospital Ramón y Cajal using this technology with good results in imaging diagnostics, while others are just starting," he noted.

The main obstacle is that each autonomous community has its own system, which does not communicate well with others. "It's like having seventeen islands of information that do not connect. Without the ability to share and analyze data jointly, AI cannot function properly," Fraga Pedroche stressed. To overcome these limitations, he recommended strengthening healthcare professionals in this field and "creating safe testing environments where we can experiment with these technologies before using them with real patients," among other measures.

Science hubs as key innovation drivers

When innovating and researching in fields like AI and biotechnology, science hubs are key, providing ready-to-use infrastructure, critical services, and a community in one environment. This was highlighted by **SID (Science & Innovation Districts) co-CEO Pilar Gil**, who illustrated the model with "ecosystems like SID Madrid and SID Barcelona that integrate laboratories, offices, and operational support so that research and

collaboration translate into real innovation in an increasingly competitive sector in Spain and Southern Europe."

According to Pilar Gil, the future of biotechnology infrastructures is shaped by private and flexible facilities "that can adapt to sectors as diverse as health, food, or sustainability without the timelines or investment required to build a dedicated center." She stated, "This trend promotes the development of versatile, certified spaces capable of offering everything from modular laboratories to pilot production areas, fostering faster and more sustainable scientific innovation."

Regional excellence: Euskadi

At the regional level, Euskadi is positioned as a compact, connected, and cooperation-oriented ecosystem. **María Ribate Olazar, Head of Internationalisation and Strategy at Basque Health Cluster**, highlighted that startups, companies, technology centers, the public healthcare system, and supporting institutions work in a coordinated manner, "achieving a level of integration rarely seen in other European ecosystems."

Ribate Olazar also stressed that Euskadi not only participates in the international biotech scene but is already recognized as a reference hub in biotechnology and health in Europe. This recognition, she emphasized, "is the result of collective effort and a commitment to a model that combines cutting-edge science with structured collaboration."