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# THE ROLE OF ADVANCED DIAGNOSTICS IN SHAPING THE FUTURE OF THE EU BIOTECH LANDSCAPE

*A White Paper prepared by the EUCOPE Advanced Diagnostics Working Group*

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# The Role of Advanced Diagnostics in Shaping the Future of the EU Biotech Landscape

## The value of supporting an advanced diagnostics ecosystem

Advanced diagnostics play an increasingly critical role in the EU biotech landscape by driving further research, increasing our understanding of human genomics and through the identification of new disease biomarkers. Advanced Diagnostics allow for the development and delivery of new personalised treatments, offering improved patient outcomes, particularly in areas of priority for the European Union like cancer and rare diseases. However, advanced diagnostics have not yet been fully exploited and supported in Europe and adoption is lagging behind other regions globally[1].

In the broader biotech ecosystem, advanced diagnostics act as enablers of innovative therapies by providing the necessary data and evidence for the development of personalised treatments. To secure the EU's position as a global leader in healthcare innovation, the recent Draghi report and the mission letter to the Health and Welfare Commissioner Olivér Várhelyi stress the need to prioritise biotechnology and biomanufacturing under the EU Biotech Initiative[2, 3]. Here, advanced diagnostics can play a key role.

As highlighted in the Draghi report, the EU currently faces significant challenges compared to other regions in the form of slow regulatory frameworks, complex pricing and reimbursement (P&R) procedures due to the fragmented requirements across Member States, and much lower levels of funding available for innovative technologies[2]. The insufficient funding for advanced diagnostics and slow and inefficient reimbursement pathways for advanced diagnostics has also been identified as a challenge in the European Parliament's report on Europe's Beating Cancer Plan[4].

To address these gaps, investment in advanced diagnostics should be prioritised as part of the new EU Biotech Act. A vibrant European advanced diagnostics ecosystem will attract companies to invest in surrounding infrastructure, create high-value jobs, and will create additional opportunities for leveraging genomic data in healthcare, ensuring that the EU remains competitive in the rapidly evolving global biotech landscape.

## Leveraging the important role of advanced diagnostics to the biotech sector

Investments in advanced diagnostics unlock significant job creation potential within the biotech and diagnostics sectors, by creating additional high-value employment opportunities across Europe. However, despite offering a potential area of growth, the EU has fallen behind in exploiting the commercial potential of genomics testing and is being outpaced by other regions such as the United States. The unfavourable ecosystem in the EU means that the smaller advanced diagnostic companies often first commercialise their products outside of Europe and only 21 percent of genomics companies are located in Europe compared to 63 percent in the U.S[5].

**Prioritising research, development, and innovation in advanced diagnostics, which have enabled the discovery of numerous genomic predictive biomarkers used in today's treatment decision-making, especially in oncology, will enhance patient care and stimulate economic growth**[6]. In the U.S., federal research funding for human genetics and genomics reached $3.3 billion in 2019, leading to the creation of nearly 166,000 academic and industry jobs, supporting more than 850,000 total jobs. Each direct job in this sector supports an additional 4.12 jobs in the broader economy. The industry's direct economic activity exceeded $108 billion, ultimately contributing more than $265 billion to the U.S. economy. **Every $1 invested in human genetics and genomics generated an additional $1.45 in economic output, with a return on investment (ROI) of 4.75 to 1**[6]. Increased public and private investment in this area in Europe could yield similar economic benefits, fostering new job opportunities in genomics, bioinformatics, data processing, and healthcare services. These are interconnected fields that are critical for the collection, analysis, and utilisation of diagnostic data, creating an ecosystem where new roles in data science, clinical research, and precision medicine will emerge.

Supporting advanced diagnostics means not only building a healthier population but also fostering a robust, knowledge-based economy with sustainable, high-skill jobs. **A vibrant advanced diagnostic ecosystem can position the EU as a global leader in biotech innovation, attracting further investment in biotech leveraging the EU's research and knowledge in this field.**

**The lack of clarity regarding regulatory pathways and the prospect for appropriate reimbursement is a significant barrier to commercialisation in the EU.** Advanced diagnostic manufacturers are facing significant market access barriers in Europe with reimbursement and funding models generally slow to adapt advanced diagnostics and relying on pharmaceutical companies paying for precision tests. This results in patients having access to advanced diagnostics through the public healthcare system with a 5-to-10-year delay from initial launch[7].While the U.S. human genetics and genomics industry generated $15.5 billion in federal tax revenue in a single year, far surpassing its $3.3 billion in public investment, Europe has yet to fully capitalise on its own potential[8]. The healthcare budget set aside for advanced diagnostics is often a fraction of what is required, with countries having significant differences in levels of investment. **To support the advanced diagnostics ecosystem in Europe, it is key to ensure sufficient funding and timely reimbursement. Reimbursement decisions must be** made faster and **implemented in** a similar **time frame** and model **as that of access to medicines**, where companies are able to apply for reimbursement.

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| **Streamlining pricing and reimbursement processes** | • *Propose a new EU directive that reduces the delays in placing new advanced diagnostics on the market, where companies can apply for reimbursement with timebound procedures for reimbursement decisions.*<br>• *Support the development of streamlined and standardised Health Technology Assessment (HTA) requirements tailored for advanced diagnostics to ensure consistency and efficiency across Member States.*<br>• *Support the development of value frameworks for advanced diagnostics that reflect the benefits for patients and healthcare systems, so that funding is increased to cover the full costs of tests for patients.* |

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| | • *Leverage the European Health Data Space (EHDS) to support faster access for patients to commercial tests by gathering Real-World Evidence (RWE) on the cost-effectiveness of advanced diagnostics in the real-world setting, as is currently done with the innovative funding scheme in France (RIHN 2.0.).* |

## Supporting commercialisation of advanced diagnostic companies to foster the growth of European biotech clusters

Advanced diagnostics should be integrated into the EU's biotech landscape because it is key for fostering biotech clusters, which drive innovation and economic growth. Advanced diagnostics serve as a vital bridge between research, clinical applications, and market-ready solutions, and should be strategically supported within these clusters. The EU can enhance collaboration between research institutions, industry, and healthcare providers by embedding advanced diagnostics into biotech clusters, thus creating a robust network that accelerates the development of new innovative diagnostics and pharmaceuticals in Europe.

New advanced diagnostics companies, collaborating within biotech clusters, benefit from shared resources, pooled expertise, and improved access to funding. Such an integrated ecosystem can strengthen the EU's global competitiveness in biotech by fostering a landscape where new diagnostic solutions can be rapidly developed, tested, and deployed, ultimately enhancing healthcare outcomes and reinforcing the EU's standing as a leader in biotech innovation.

Despite European institutions playing an important role in supporting R&D – with one-third of the total R&D expenditure in EU being publicly funded – **the EU lags behind the US in access to capital for seed-stage and early-stage companies**[9]. Without existing commercialised products, advanced diagnostic companies require capital to develop their technologies; capital is needed to develop the assay and supporting software and to obtain clinical utility data. Compared to companies in the US, advanced diagnostic companies in the EU are struggling to cope due to less access to capital. Due to a lacking European ecosystem, technologies initially developed in European labs are commercialised by companies with greater access to US capital markets – often those located outside of the EU[10].

To remedy this, **governments should invest funding to support the move of advanced diagnostics from the research setting into the clinical setting**. For instance, through the allocation of government investments to genomics, advanced diagnostic companies have succeeded in attracting capital and developing early commercialisation potential. Countries such as the UK and France have introduced national policies designed to increase investments in genomics and greater diagnostic capacity. The UK launched Genomics England in 2013 and ran the 100.000 Genomes Project, while France launched its public genomics initiative in 2016, saying it would invest €670 million over the first five years. In 2025, France further expanded its commitment to genomic medicine with the launch of the France Genomic Medicine Initiative, aiming to accelerate the integration of genomics into clinical practice and strengthen national capabilities in precision medicine. **To incentivise further innovation in genomic sequencing, the EU should support the entrance of new companies and technologies, with a European market that recognises the value of advanced diagnostics.**

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| **Leveraging public-private partnerships** | • *Establish funding opportunities that encourage collaboration between industry, academia, biotech, and other high-tech sectors (e.g. bioinformatics) to facilitate the translation of advanced diagnostics from research to the clinical setting.*<br>• *Develop a roadmap for the new reference networks for cancer established under Europe's Beating Cancer Plan to enable collaboration with existing innovation hubs in life sciences and new commercial actors to spur establishment of additional hubs.*<br>• *Establish specific funding and risk capital for advanced diagnostics at both EU and national level to facilitate the creation of new advanced diagnostic companies at early stage.*<br>• *Provide additional tailored funds and tax incentives for the development of cutting-edge products, and public investment to enable technological transformation (e.g. data analytics and digital tools).* |

## Enhancing the EU's competitiveness by attracting companies to perform research in Europe

A well-supported advanced diagnostics ecosystem is critical to enhancing the EU's competitiveness by attracting global clinical trials to the region, positioning the EU as a hub for clinical research. By investing in advanced diagnostics infrastructure, Europe can close the relative gap with other global regions. Increasing the number of clinical trials performed in Europe, will not only drive further innovation in Europe but also provide European patients with earlier access to potentially life-changing, innovative therapies in development, especially personalised cancer treatments.

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| **Fostering a competitive ecosystem for advanced diagnostics** | • *Establish structured opportunities for advanced diagnostic companies to engage with regulators, enabling tailored guidance on regulatory pathways and on early evidence generation, which in turn will enable manufacturers to shape studies to meet regulators evidence requirements.*<br>• *Make Europe a more attractive location for organising clinical trials by investing in state-of-the-art genomic sequencing infrastructure, including comprehensive genomic profiling, to capture all mutations relevant for innovative drug candidates in development.* |

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