Diagnostics
Special Report 2024

HEALTHCARE
BUSINESS INTERNATIONAL

EXECUTIVE SUMMARY

The diagnostics landscape is undergoing a seismic shift, driven by a convergence of technological innovation, evolving market dynamics, and changing healthcare needs. As national markets approach consolidation saturation, forward-thinking players are increasingly looking across borders for growth opportunities, despite persistent regulatory challenges.

The HBI Diagnostics Special Report 2024 explores key business and investment trends within the sector:

- Automation and AI: With only 5% of the diagnostic labs market currently leveraging these technologies, there is immense untapped potential. Early adopters stand to gain significant efficiency improvements and enhanced diagnostic accuracy.
- Operational Innovation: New business models are reshaping the industry. 'Dark labs', teleradiology, and the rise of 'phygital' practices are transforming traditional operations, while at-home testing continues to evolve despite growing pains.
- Workforce Challenges: The sector is grappling with a severe shortage of healthcare professionals, with Europe alone facing a deficit of two million workers. The report examines strategies to address this critical issue.
- Market Dynamics: Shifting landscapes across Europe are creating new opportunities. For instance, the UK is seeing increased private sector involvement in response to NHS waiting times.
- Volatility and Adaptation: In an increasingly unpredictable environment, success will depend on providers' ability to innovate, automate, and position themselves as essential partners within the broader healthcare ecosystem.

The report also includes some highlights from our recent news reporting on the segment, and infographics and data on the state of play within Europe's Diagnostic Imaging and Laboratory markets.

As diagnostics continues its rapid evolution, the industry faces the dual challenge of harnessing transformative technologies while maintaining a steadfast focus on high-quality patient care.

Our report offers invaluable reporting and insights for stakeholders navigating this complex and dynamic landscape, highlighting both the obstacles and opportunities that lie ahead.

Exploring the European diagnostics sector

Report Contents - While only the first three sections are available in this Executive Summary, the complete report will have the full chapter list.

The European diagnostics sector is undergoing significant transformation, driven by technological advancements, changing demographics, regulatory reform, and perhaps most importantly, the evolving healthcare needs of an ageing population.

Market evolution and growth

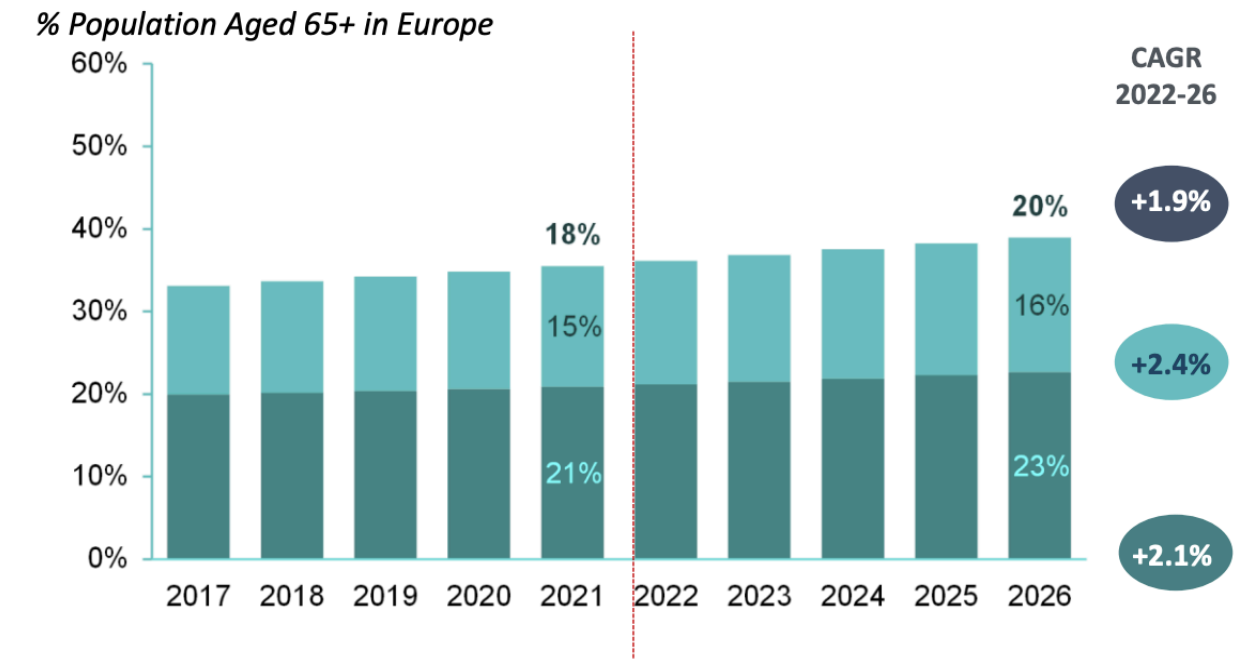
The diagnostics market in Europe is large, representing about 29% of the global market, and forms a substantial and growing segment of the healthcare industry, with notable

variations across countries.

Growth is steady, if not spectacular. In 2022, the European In Vitro Diagnostics market was valued at over €8.3 billion, compared to a global market value of €47 billion, with a CAGR of 2.9% from 2015 to 2030. Infectious disease diagnostics hold the largest share of this market (71%).

In Germany, Europe's largest healthcare market, the laboratory diagnostics sector alone was estimated to be worth around €15 billion in 2021 due to a huge boost from Covid testing, with for-profits accounting for approximately €10 billion of that figure.

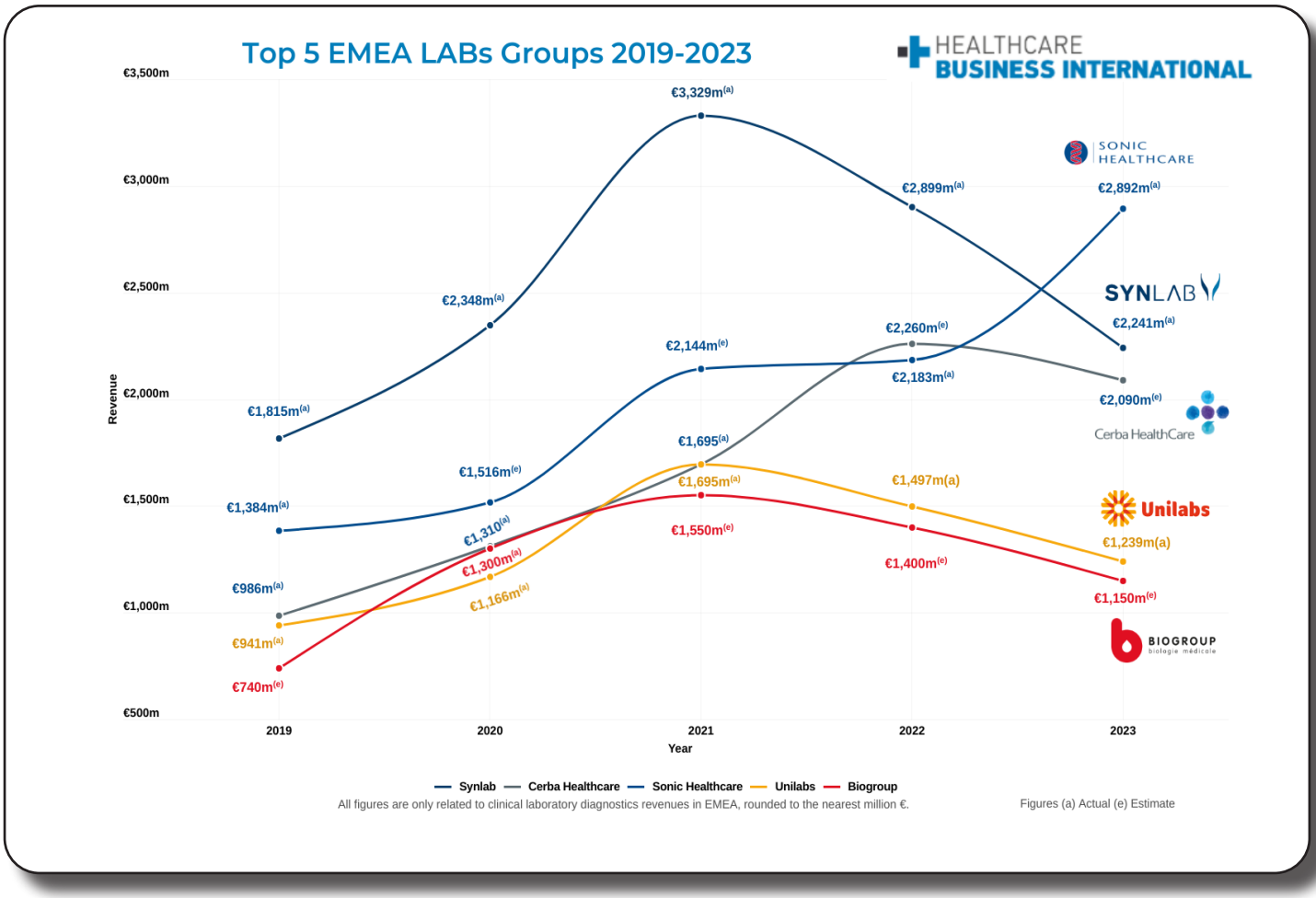
This market has shown resilience, with a long-term growth trend of 3-4% per



The demographic opportunity and challenge within Europe, as presented by Evidia Group COO Zisis Sotiriou at HBI 2024

annum, driven by an ageing population and the introduction of new types of tests. The UK's laboratory diagnostics market is meanwhile expected to grow at a compound annual growth rate (CAGR) of 7.81% until 2027.

In France, the entire imaging sector was worth around €7.4 billion in 2022, with the for-profit segment accounting for about €4.9 billion. The French laboratory sector has also seen significant growth, with total expenditure reaching €11 billion in 2021, up from €6.8 billion in 2019. The for-profit sector accounts for about 60% of this total.



Italy boasts a large for-profit imaging sector, while Spain's for-profit diagnostic imaging sector comprises over €1 billion of the market.

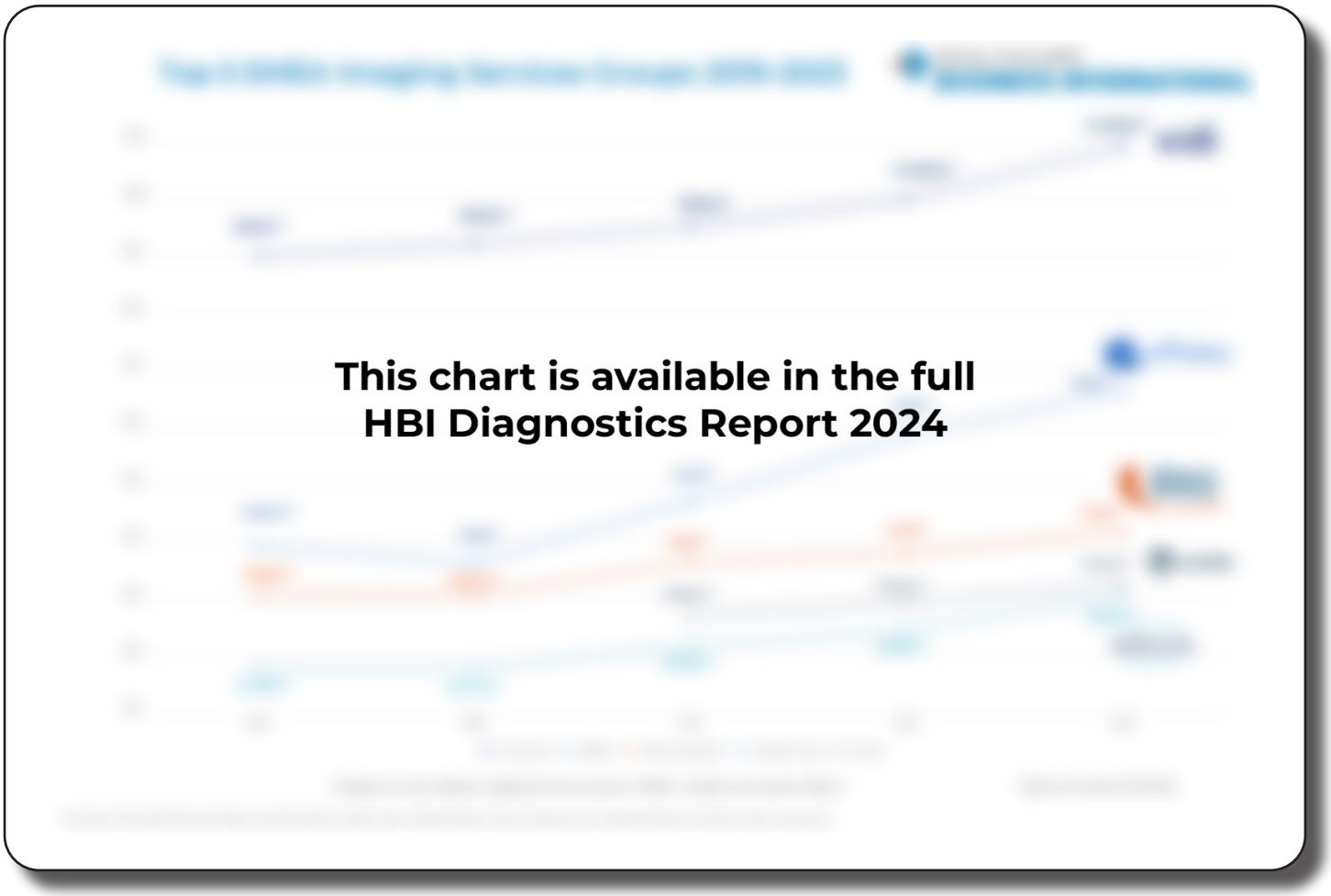
The Spanish sector is highly competitive, with strong downward pressure on prices, yet it continues to grow, particularly in the private pay segment.

Other countries, such as the Netherlands, instead see a market largely dominated by non-profit providers.

Post-COVID financial landscape

The COVID-19 pandemic had a profound impact on the diagnostics sector, leading to unprecedented growth in 2020 and 2021. In the UK, the laboratory sector's total revenue more than doubled, reaching £7.7 billion in 2021.

The for-profit sector grew by about 50%, reaching €871 million. However, as COVID testing has declined, many countries experienced a normalisation of revenue. In the UK, the for-profit sector's revenue dropped to approximately €750 million in 2022



as it returned to pre-COVID growth trends.

This pattern is mirrored across Europe. In Germany, COVID testing added about €4 to €5 billion to the sector in 2021, but revenue decreased as testing has wound down.

Similarly, in Spain, total revenue of the labs sector reached €6.2 billion in 2021, more than double the 2019 figure of €3.03 billion.

All countries have seen some normalisation following the peak of the pandemic.

Consolidation and investment

The European diagnostics sector is experiencing varying degrees of consolidation across different countries. The laboratory sector is attracting private equity and infrastructure funds due to high EBITDA-to-cash conversion rates.

The €60 billion medical imaging sector is also consolidating, driven by an ageing population and increased outsourcing, and facing radiologist shortages and tariff pressures.

The veterinary lab testing market is

also undergoing consolidation.

In France, the laboratory market is highly consolidated, with the top three players holding around a 40% market share of the for-profit sector, and the top 10 players having around a 65% market share. The number of companies in the sector has shrunk dramatically over the longer term, from about 5,000 in 2008 to around 400 in 2022.

Germany's for-profit laboratory market is approximately 75% consolidated, with the five largest groups commanding roughly a 40% market share of the for-profit sector. The top groups include Limbach Gruppe, Sonic Healthcare, Synlab, and Amedes Group.

In contrast, the imaging sector in some countries has remained fragmented.

France's imaging market is still largely unconsolidated, with the top five players holding less than one-eighth of the market. The picture in Germany is similar.

This presents significant opportunities for mergers and acquisitions, although regulatory barriers in some countries may limit further consolidation in outpatient care.

Germany is currently undergoing significant healthcare reforms that, while more limited in scope than the Health Minister Karl Lauterbach first intended, will still need to be observed and taken into consideration by investors and providers.

The UK's for-profit labs sector is meanwhile highly consolidated, with Sonic commanding over 50% of the total for-profit market.

Together, Sonic, Synlab, and Source Bioscience hold over 90% of the entire for-profit sector.

Technological innovation and new efficiencies

Technological advancements are driving significant changes in the diagnostics sector. In laboratory diagnostics, automation and artificial intelligence (AI) are improving efficiency and accuracy.

According to Deloitte, in 2020 Europe spent about €265 per person on medical technology, representing ~7.6% of total healthcare expenditure. In vitro diagnostics (IVD) accounted for ~0.8% of this, while medical devices, including imaging, comprised the remaining ~6.9%. Despite IVD tests influencing up to 70% of clinical decisions, they represent a small fraction of healthcare spending.

According to Automata's Joe Stringer

at HBI 2024, only about 5% of the diagnostic labs market is genuinely automated, indicating substantial room for growth and efficiency gains. Robotics brings further opportunities, as it can decrease manual touch points while radically increasing throughput.

In imaging, AI applications are becoming more prevalent. Antoine Jomier, CEO & Co Founder of Incepto Medica, a platform for imaging AI applications, predicted at HBI 2024 that by 2025, 80% of imaging exams will be assisted by some form of AI. This technological shift promises to enhance productivity, with Jomier believing that it has the potential to lead to a 30-40% time saving for radiologists and a 3-7 percentage point increase in EBITDA for radiology companies.

The adoption of cloud-based systems is also transforming the sector. Currently, only about 2% of the imaging industry is on the cloud, but this is expected to change rapidly in the next 5-10 years, unlocking new capabilities and efficiencies.

Delivery models are changing, with diagnostics companies trying to make their services more convenient and accessible. According to a 2022 Deloitte report, 57% of 250 surveyed diagnostic companies in Europe are shifting towards more innovative, patient-centric solutions, moving away from centralised laboratories. Although innovations like at-home testing have advanced, they have not yet reached their full potential, according to HBI 2024's laboratory diagnostics panel.

Workforce challenges

A persistent theme across European diagnostics is the shortage of qualified professionals, particularly radiologists and pathologists.

In the UK, there have been projections of a 39% shortfall in consultant radiologists by 2026 without further investment. France faces a similar challenge, with some areas having 20 times fewer radiologists per head than big cities.

In Germany, the shortage of pathologists is expected to worsen in the coming years as they retire at a faster rate than new ones are trained. This shortage is driving innovation in workflow optimisation and the adoption of AI to augment human capabilities.

Regulatory and tariff pressures

The regulatory landscape varies significantly across Europe, influencing market dynamics and investment opportunities. In France, recent regulatory changes have opened up possibilities for private equity investment in imaging centres, potentially accelerating consolidation.
In Germany, while proposed regulations to restrict private investment in outpatient clinics have

not materialised as first expected, regulatory reforms are still emerging. The country has various kinds of limits and ceilings on the sector, including both revenue and volume controls for statutory insurance-funded tests.

Tariff pressures remain a constant challenge across Europe. In Germany, laboratory reimbursement rates have been repeatedly cut over the past three decades, and have been cut again, to the chagrin of the VDGH, the trade association for diagnostics manufacturers and life science research companies in the country.

In France, pre-COVID tariffs had meanwhile been decreasing by 2-3% per year.

Similar pressures are observed in other countries, including the Netherlands, where non-profits receive favourable reimbursement rates versus for-profit groups.

Across Europe, providers are seeking efficiency gains and economies of scale in search of profitability.

We explore the role of automation in seeking to achieve that goal later in this report.

There is European level reform to factor into future decision making, including the effects of the EU's new AI Act, which has the potential to majorly impact diagnostic imaging and device companies in particular, as they seek to leverage the benefits of artificial intelligence tools. We explore this legislation later in this report.

The future

The European diagnostics sector is at a pivotal juncture. Following a period of post-COVID normalisation, consolidation and economies of scale, technological innovation, and an evolving regulatory landscape will define the sector's future.

While challenges persist, particularly in workforce shortages and tariff pressures, opportunities for growth and efficiency gains through consolidation and technological adoption are substantial and growing.

The sector's future will be shaped by several factors — the continued adoption of AI and automation technologies, the shift towards personalised medicine and genetic testing, the expansion of teleradiology and 'phygital' hybrid services, and the as yet unfulfilled potential for direct-to-consumer and at-home testing options.

As the sector navigates these changes, its ability to adapt to regulatory pressures, invest in new technologies, and address workforce challenges will be crucial in shaping the future of healthcare delivery across Europe.

HBI INTELLIGENCE

THE LEADING DIAGNOSTIC IMAGING AND LABORATORY PROVIDERS IN EUROPE

HBI Intelligence's provider database provides the most comprehensive view of Europe's healthcare companies, providing a range of insights, from their owners and investors, to in-market revenue splits.

In the below tables we share five of Europe's leading diagnostic imaging and five laboratory providers, with European revenues of more than €100m in 2022. In the full report we share the list of every company with European revenues of more than €100m in 2022

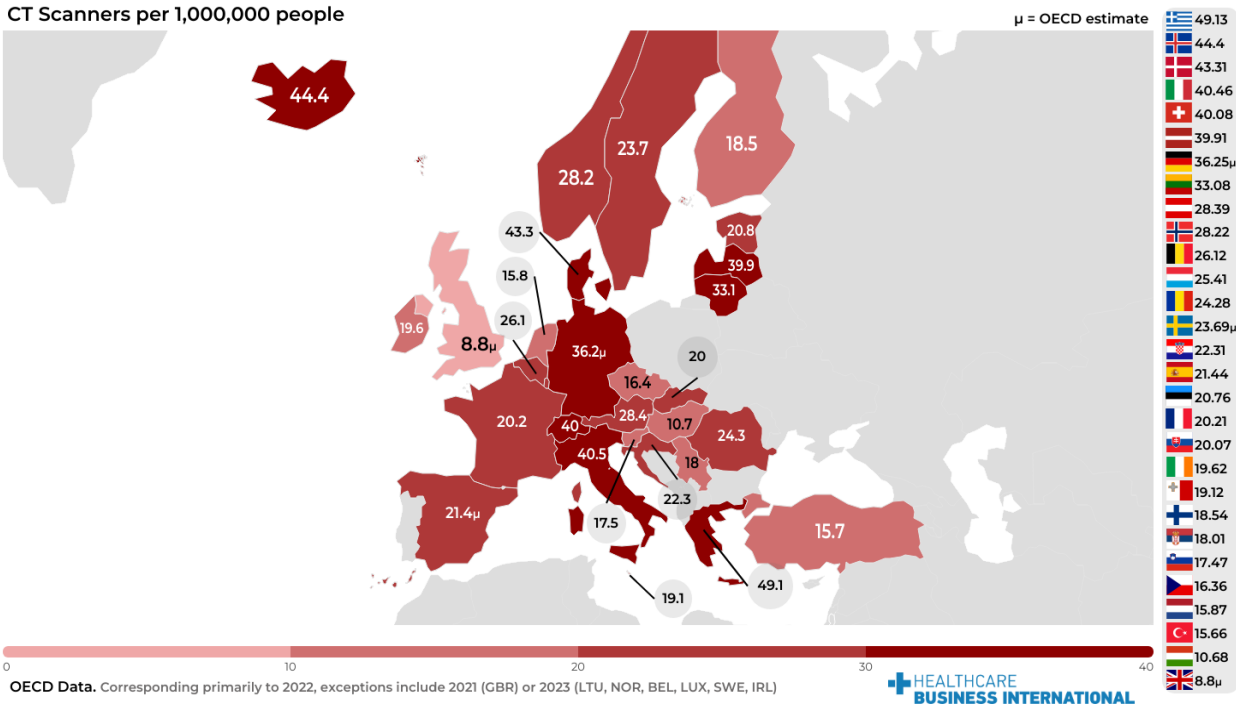
Imaging companies >€100m in service revenue, Europe

Company	Invested in	Investors	Country of origin	Total 2022 company sales, €million	Imaging Services, €million
Groupe Vidi	2023	Kartesia	France	**1000**	**1000**
Affidea International	2022	Groupe Bruxelles Lambert	Netherlands	**745**	**594.6**
Alliance Medical	2023	iCON Infrastructure	United Kingdom	**440**	**440**
Evidia	2019, 2021	Deutsche Beteiligungs AG, EQT AB	Germany	**293**	**293**
InHealth Group	-	-	United Kingdom	**285.7**	**285.7**

Laboratory companies >€100m in service revenue, Europe

Company	Invested in	Investors	Country of origin	Total 2022 company sales, €million	Laboratory services, €million
Synlab	2015	Norges Bank Investment Management, Cinven	Germany	**3250.5**	**2850.4**
Cerba Healthcare	2017, 2021	PSP Investments, EQT AB	France	**2260**	**2260**
Sonic Healthcare	2022	Santerre Health Investors	Australia	**4,400.4**	**2,182.6**
Limbach Gruppe	-	-	Germany	**1438.7**	**1438.7**
Biogroup	2017, 2018, 2020	Idinvest Partners, CDPQ, Straco	France	**1400**	**1400**

DIAGNOSTIC IMAGING CAPACITY VARIES SIGNIFICANTLY ACROSS COUNTRIES — WITH WHAT IMPACT?



- Diagnostic imaging capacity varies widely among countries, generally correlating with wealth.
- Per capita healthcare expenditure, not imaging capacity, appears to more strongly predict avoidable mortality.
- Future screening programs may increase imaging demand, likely impacting mortality rates.

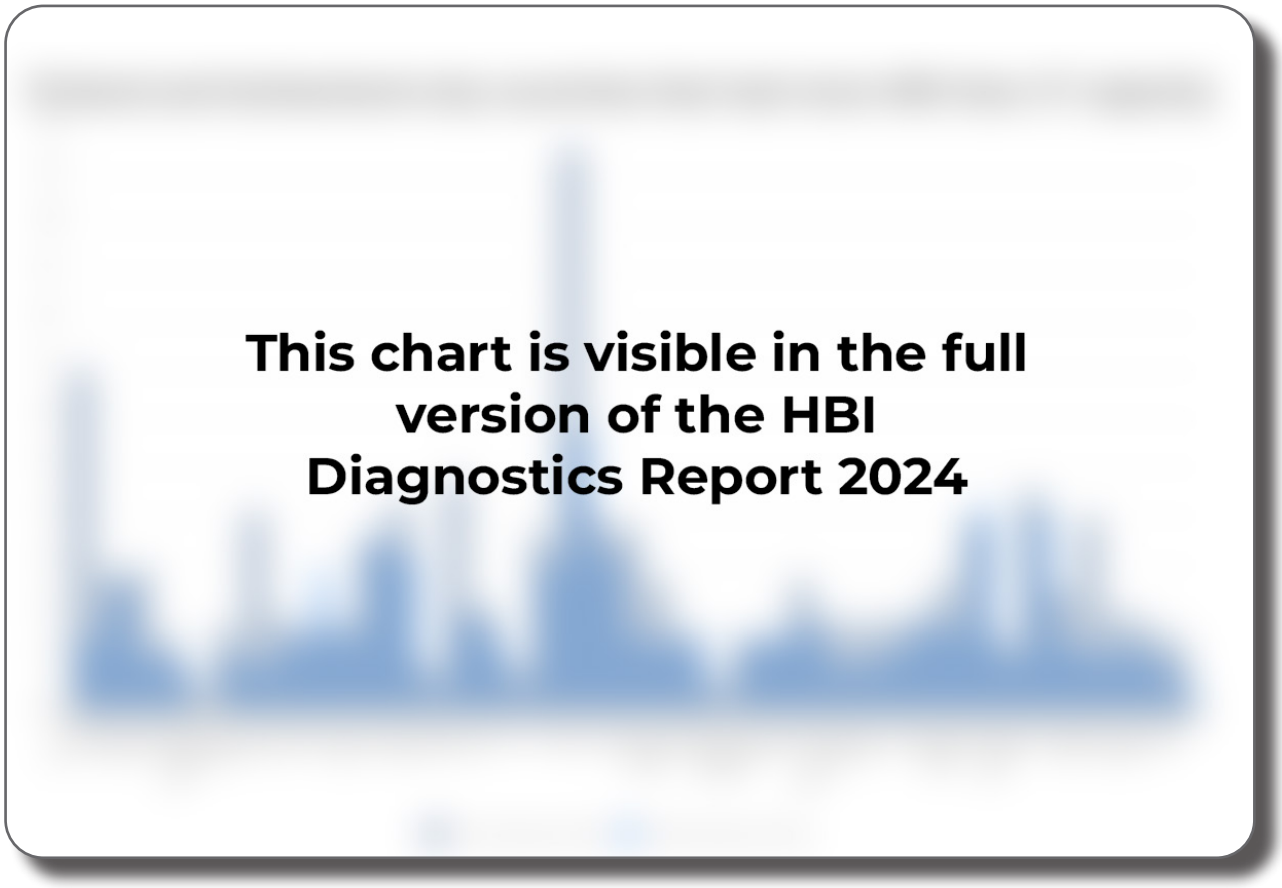
Diagnostic imaging capacity varies significantly by country, even amongst rich nations. Using OECD data, we explored how the number of CT scanners and MRI scanners per million inhabitants varies between 39 OECD+ countries, and whether this has an impact on avoidable mortality for 27 of those countries.

We used 2019 data, to avoid any distortion from COVID.

Rich countries tend to have greater diagnostic imaging capacity than poorer countries. The US has almost seven times more CT capacity per head than Mexico, and almost 14 times more MRI capacity per head.

Germany has 3.7 times the per-head CT capacity as Hungary, and seven times the MRI capacity. Japan has by far the most capacity of both CT and MRI scanners. **However, there are some notable outliers to this trend.**

Brazil and several Eastern European countries have significantly greater capacity than Israel. Canada also has much smaller capacity than you would expect, based on its wealth.

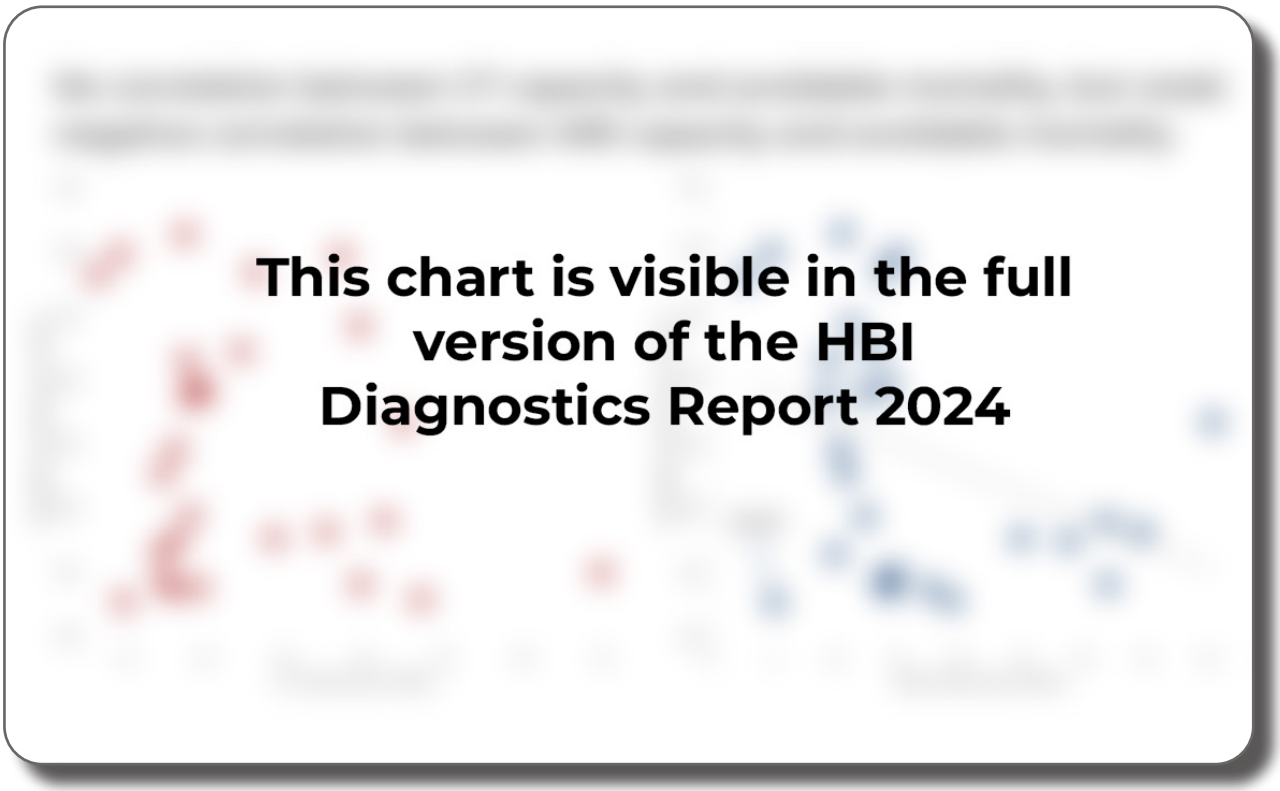


Another striking trend is that almost every country has significantly greater CT capacity than MRI capacity.

Out of the 39 countries, Finland and Switzerland were the only ones to have more MRI than CT scanners per head. The likely explanation for this is that, of the two modalities, MRI is the more expensive.

Do the differences in CT and MRI capacity have an impact on avoidable mortality?

At first glance it would appear that MRI capacity does, whilst CT capacity does not: there is a weak negative correlation between MRI capacity and avoidable mortality, but no correlation between CT capacity and avoidable mortality.

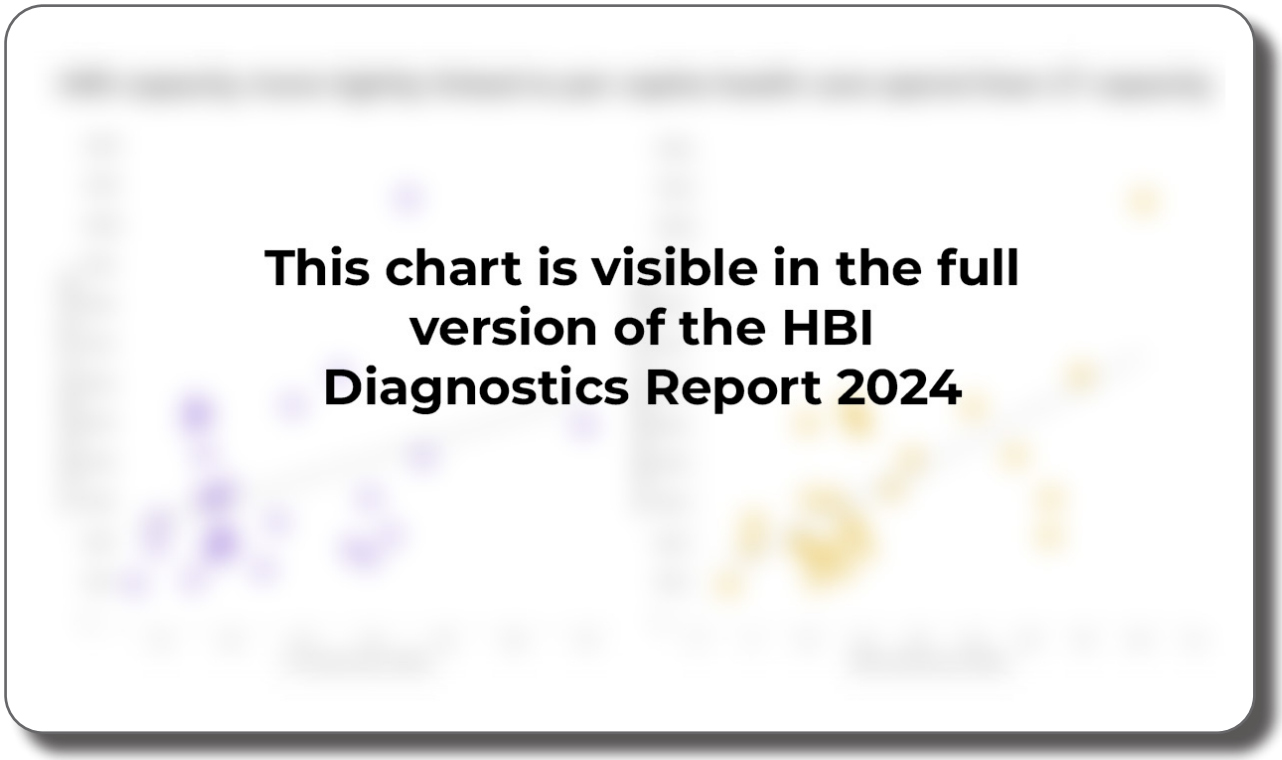


But when you control for per capita expenditure on healthcare by country, the picture becomes quite different. Running a multiple regression with CT capacity, MRI capacity and 2019 per capita health expenditure (in purchasing power parity-adjusted dollars) as predictors for avoidable mortality in 2019, only per capita health expenditure is anywhere close to being a statistically significant predictor.

The correlation between MRI capacity and avoidable mortality appears to be due to MRI capacity being much more tightly linked to a country's per capita health expenditure.

It's particularly notable that out of the countries analysed Israel – which is perhaps the only country in the world where a sophisticated AI-enabled preventive healthcare model is being practised at scale – has one of the lowest capacities of both MRI and CT and yet also had the lowest rate of avoidable mortality in 2019.

Does this mean that countries with lower MRI and CT capacity such as Israel would



be wasting money if they invest in more machines? Not necessarily. The diseases where MRI and CT machines have the biggest potential to reduce mortality tend to be more prevalent amongst the elderly — cancer, cardiovascular disease, neurological disorders etc.

Antoine Jomier, CEO and Co Founder of Incepto Medical, a platform for AI applications for radiology, explained to HBI 2024 attendees that screening programs for cancer are beginning to be implemented in some countries, and that this will be one of the biggest drivers of future demand for imaging:

"There is clear evidence that if you do lung cancer screening, you have a cancer mortality reduction of 17%. For all types of deaths, it's a 4% reduction. From a cost effectiveness standpoint, it's very well documented. So all the public payors and states are thinking about implementing it."

Most countries will need greater MRI and CT capacity as their populations age to service the big increase in volumes required by screening programs. But in order to achieve the desired reduction in mortality, they will also need the workforce capability to manage the additional capacity, and enough clinical capacity for treatments such as chemotherapy and radiation therapy for cases resulting from screening programs.

So it is possible, but by no means certain, that in the future MRI and CT capacity will become statistically significant predictors of avoidable mortality.

Please get in touch with us

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- Impact, Sustainability and Future Workforce
- Exit strategies, value creation and developing strong leadership
- Digital Transformation and AI
- Personalised medicine, consumer-driven healthcare and treating non-communicable disease

Covering key healthcare verticals

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