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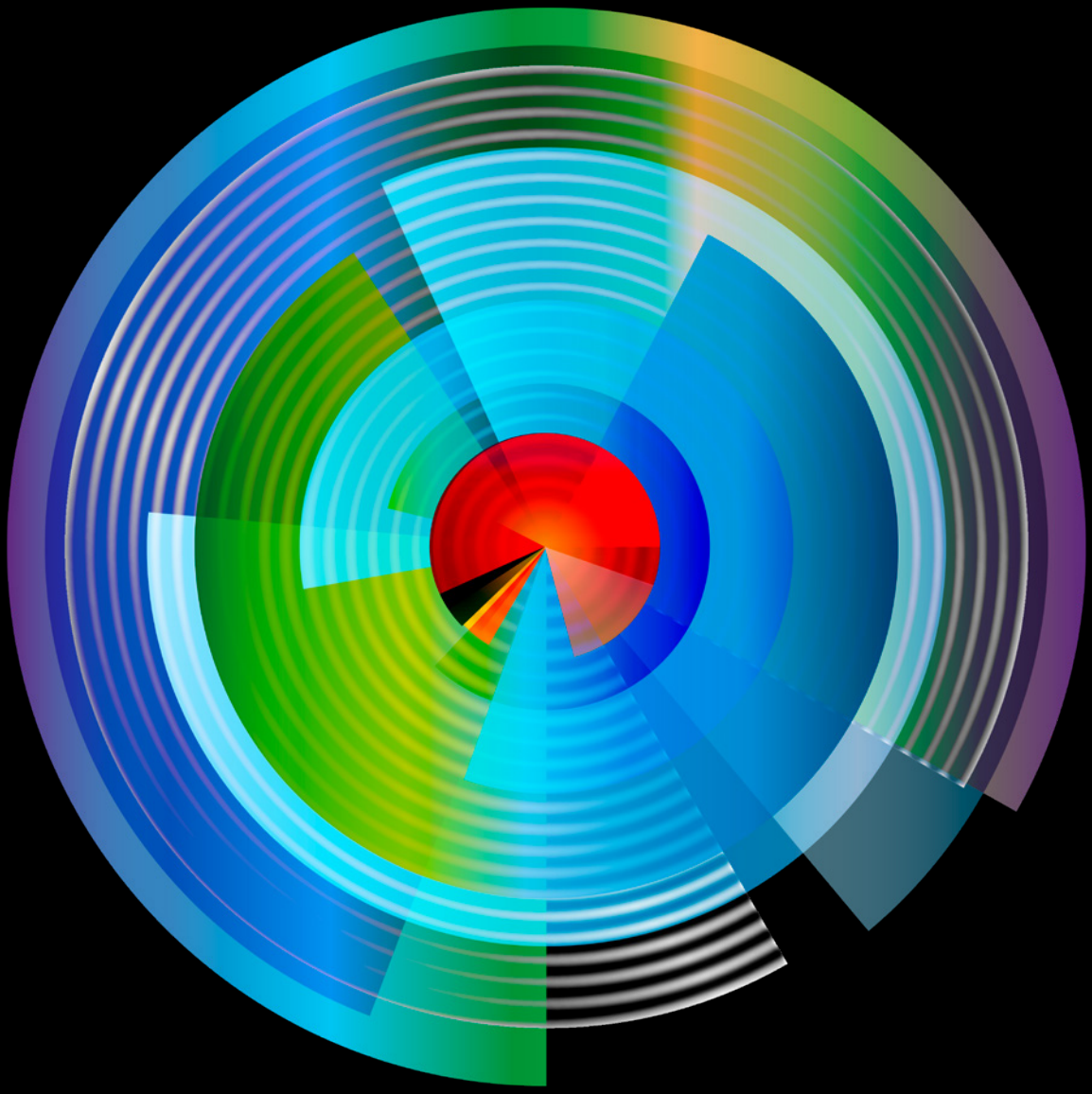

The future of diagnostics
Technology driven personalised and preventative healthcare in Europe

October 2022

Deloitte Centre *for* Health Solutions

Contents

Foreword

Welcome to the Deloitte Centre for Health Solutions latest report, *The future of diagnostics: Technology driven personalised and preventative healthcare in Europe*. This report explores the evolving role of diagnostics in shaping new clinical pathways and how the adoption of disruptive diagnostic technologies can help healthcare systems transition from volume-based to value-based care. It envisages a future in which diagnostics are crucial drivers of more predictive, preventative, personalised, participatory (4P) care.

Diagnostics play a pivotal role across the entire healthcare continuum from screening, detection and prognosis to patient stratification and condition monitoring. Diagnostic tests affect most healthcare decisions: they support clinicians by providing an accurate diagnosis and prescribing the correct treatment. Earlier access to diagnostic tests can help avoid adverse health outcomes and the cost of late-stage or unnecessary treatment. Diagnostics can also enable a shift from reactive, episodic treatment, to predictive and proactive integrated care.

Appropriate and timely diagnostic testing can also provide realisable cost-saving opportunities for healthcare systems everywhere. A wide body of research shows that early detection and diagnosis leads to better patient outcomes for all major life-threatening diseases, from cancer and coronary heart disease to respiratory and infectious diseases. This results in considerable savings in treatment costs. Evidence-based diagnostic solutions empower doctors to make the right decisions, allow patients to have more control over their own health, and give payers and policymakers the confidence to invest in the right solutions.

While diagnostics have always been one of the foundations of healthcare, advances in science and technology mean they are now well positioned to play a key role in revolutionising healthcare. Driving the need for innovation are growing and ageing populations, the increasing prevalence of non-communicable diseases and chronic conditions, workforce shortages and an increasingly knowledgeable and empowered consumer base. Today, artificial intelligence, automation, embedded sensors, and digitalisation are beginning to disrupt healthcare in Europe and will do so more significantly in the future.

The diagnostics industry accounts for just two to three per cent of all healthcare spending, but influences over 70 per cent of medical decision making. Changing the dial to increase the priority given to diagnostics would have the potential to improve equity of access and health outcomes for everyone, but this would require an industry-wide effort to help all stakeholders appreciate the role of innovative diagnostics within healthcare, and a concerted effort from all stakeholders to translate innovation into impact.

The future of diagnostics is one in which healthcare collaborates with academia and the diagnostics industry to harness the potential of diagnostics and realise fully the opportunities for enhancing overall standards of care and achieving optimal outcomes across the healthcare continuum. This report examines the challenges to and solutions for realising this future. It explores, in an intentionally optimistic and provocative way, what the future of diagnostics in Europe might look like. As always, we welcome your feedback.

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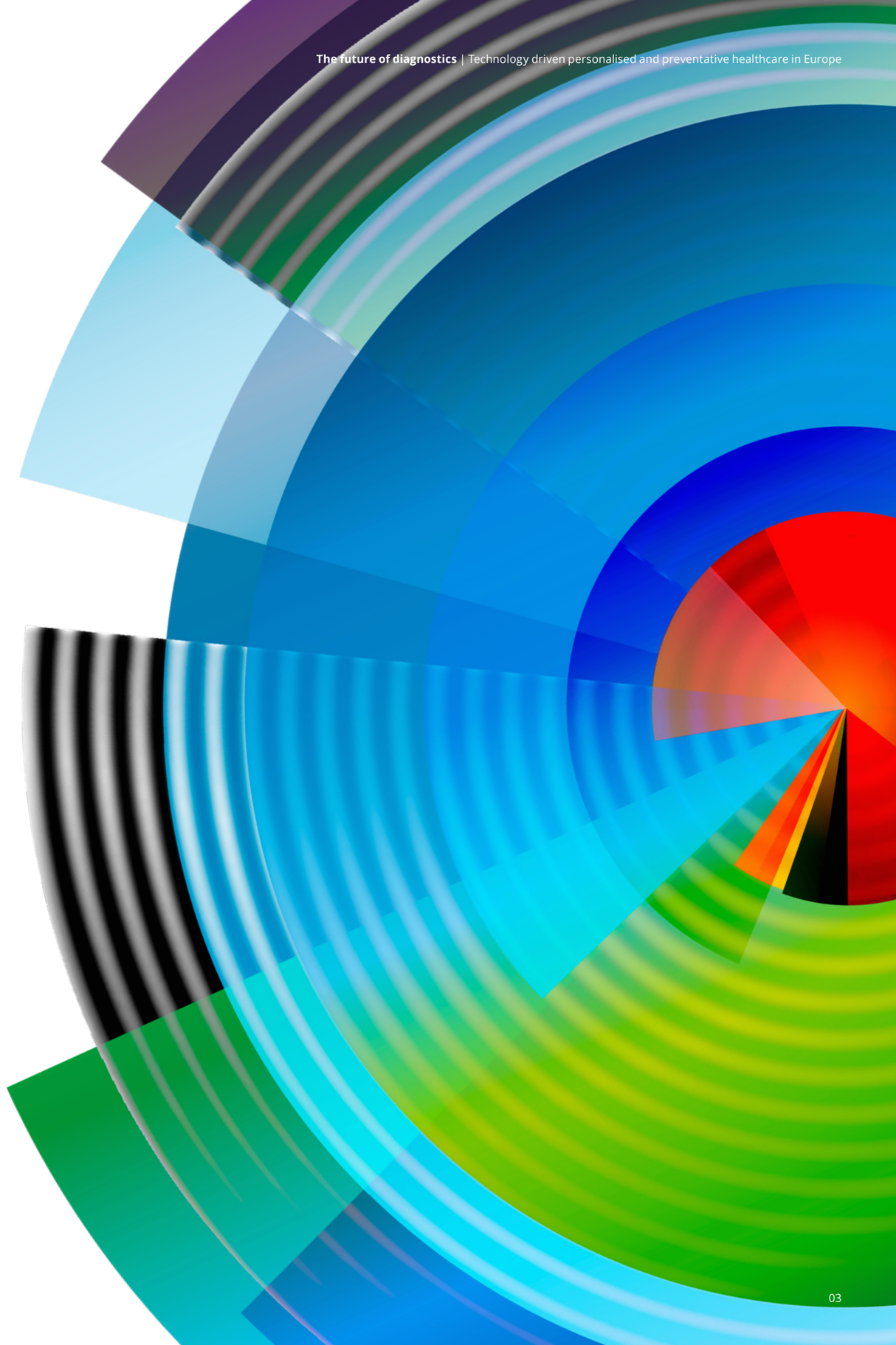

Executive summary

Appreciation of the central role that diagnostics play in European healthcare has increased substantially in recent years, but diagnostics companies still face many challenges in the design, development, funding, regulation and adoption of new products. These challenges, together with growing demands on healthcare and a shortage of skilled staff and other resources, have led to growing patient backlogs and highlighted the need for radical transformation of diagnostic services. More collaborative ways of working and rapid advances in science, technology and data analytics have catalysed innovation and created opportunities to reimagine diagnostic pathways and deliver a more predictive, personalised, preventative and participatory (4P) future for patients, and a more cost-effective future for health systems.

The diagnostics industry comprises a wide range of diagnostic devices and tests, from high value relatively low use imaging tests to low cost and high use in vitro diagnostic (IVD) tests. For many years, innovations in diagnostics have helped improve medical practice in Europe. However, inaccurate or delayed diagnosis have continued to cause harm to an unacceptable number of patients across all care settings. Today, advances in technology are transforming imaging and creating new types of in vitro and digital diagnostic tests that can improve the speed and accuracy of diagnosis and enable more timely and precise medical interventions.

The findings in this report are derived from an extensive literature review, semi-structured interviews with 40 key stakeholders from across Europe, survey responses from 250 European diagnostics companies with at least one diagnostic product in their portfolio, survey responses from 751 front-line clinical staff (clinicians), and insights from Deloitte colleagues from across the world.

Why diagnostic services in Europe need to change

Diagnostics have a vital role in shaping more efficient and effective models of patient care. Prior to the COVID-19 pandemic, demand for diagnostic services (including imaging, pathology, endoscopy and genomics), was increasing at a faster rate than available capacity. The disruption caused by the pandemic exacerbated pre-existing backlogs, strengthening the need for change. However, the pandemic also catalysed innovation across the healthcare and life sciences industry, accelerating the development and adoption of new diagnostics and shifting the location of diagnostic testing out of hospitals and centralised laboratories and closer to the patient. Among our surveyed clinicians, 57 per cent said that they were seeing this shift and 77 per cent of our surveyed diagnostics companies reported that their products were already part of this move. Clinicians currently experience a variety of challenges in being able to obtain a timely diagnosis, but most consider that adopting new diagnostic technologies will improve their ability to diagnose faster. However, the adoption and utilisation of these innovations across Europe remains slow and fragmented, and there is much still to do.

The challenges in product development and adoption

Diagnostics companies face numerous challenges in product development and in scaling adoption and growing their markets in Europe. Most diagnostics companies told us that they felt 'well' or 'reasonably well' prepared to deal with the challenges in developing innovative products, particularly in obtaining intellectual property (IP) protection and in recruiting and retaining people with the requisite skills to design and develop a product. Companies felt least prepared in being able to obtain sufficient funding and investment to develop and launch a product and in gathering enough clinical evidence to support the regulatory approval process.

The top challenge diagnostics companies faced in bringing a new diagnostic device to market was the variable digital infrastructure in healthcare (51 per cent of respondents). Furthermore, data sharing was seen as the one most important change needed to improve diagnostic services. Additionally, over 44 per cent of companies ranked healthcare cultures and attitudes to technology enabled digital transformation and the regulatory approval process in the top three challenges they face.

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While connected diagnostic technologies and a mature digital infrastructure can support the provision of timely data that enables earlier diagnosis and personalised treatment, interoperability and connectivity remain a core barrier to digital transformation and data sharing. A lack of agreed standards and frameworks continues to inhibit progress in this area.

Companies also face a variety of challenges due to the new medical devices and in vitro diagnostics regulations which came into force in May 2021 and May 2022 respectively. Both our interviewees and our survey respondents told us that the complexity of funding innovation in diagnostics, increased costs of development, increased clinical evidence requirements and bottlenecks in the capacity of notified bodies were making Europe a less attractive market for initial product launch. Solutions include improved communication and cooperation between regulators and companies in developing a clear route to regulatory approval and prioritising regulatory capacity building. To increase adoption of innovation, more effective collaboration between healthcare providers and industry is needed to improve providers and payers understanding and utilisation of the results from new diagnostic technologies, including wearables and at home testing, genomics, and AI. Diagnostics companies also need to provide robust, evidence-based assurance about the safety and security of products to regulators and the health system.

Currently, a considerable gap exists between the value that diagnostic testing can offer and the amount of funding that investors seem willing to provide. A Europe-wide ecosystem is needed to support manufacturers in obtaining funding for the development and launch of their products. Furthermore, manufacturers need to understand how best to demonstrate the value of their technology to investors pre-market.

Supply chain issues are also having a significant impact on European manufacturers, due largely to the pandemic, Brexit, and geopolitical turbulence. Our interviewees told us that they have developed multiple strategies to safeguard their supply chains, including higher levels of inventory and access to multiple sources for materials and components. In future, increased product traceability requirements and global ambitions for achieving net zero are also expected to have major supply chain implications.

Furthermore, across Europe, healthcare systems are facing significant workforce shortages, including shortages in the radiology and pathology workforce. The adoption of new diagnostic technologies can help improve efficiency and enable clinicians to make more accurate and timely diagnosis and treatnnet decisions. Our surveyed clinicians felt a lack of workforce training and skills in new technologies was a core barrier to technology adoption. While healthcare systems should provide such training, diagnostics companies could help by ensuring they provide appropriate learning materials, on-demand support, and on-site training.

A new diagnostic paradigm enabling 4P medicine

Disruptive technologies alongside advances in science and informatics are combining to transform the way diseases and other deficiencies and abnormalities are prevented, diagnosed and treated. The diagnostics landscape is constantly evolving, with the pace of change accelerating in the past few years. The diagnostics industry is now entering the fourth industrial revolution. Digitalisation, robotisation and automation are giving rise to smart laboratories and smart imaging systems that can readily handle the increasing demands from healthcare providers and consumers at greater speed and lower cost.

Our research has identified technologies that are already enhancing diagnosis, and those that are likely to transform diagnosis in the future.

Diagnostics are no longer just about detection. They have a pivotal role across the entire continuum of healthcare, from screening diagnosis and prognosis to patient stratification and treatment monitoring. New diagnostic technologies can transform care pathways and improve patient outcomes through faster and more accurate diagnosis, leading to earlier and more targeted intervention. Wearable and implantable devices can deliver continuous information that enables healthcare systems to track the health of individuals and help researchers study the effectiveness of treatments or preventive health programmes in entire populations. The future is about being able to intercept diseases early and, ideally, prevent them. This calls for an integrated network of information about individuals and populations, obtained from diagnostic devices, servers, institutions and individuals.

Among the clinician respondents to our survey, 63 per cent suggested that as the healthcare sector transitions from a focus on acute intervention to one centred around prevention and wellness, the future of diagnostics will look somewhat different in 3-5 years' time, and two-thirds think it will look 'a great deal' or 'totally' different in 6-10 years' time. To realise the future of diagnostics it will be necessary to educate and train clinicians, to enhance their understanding of research, data science and genomics and digital technologies and AI. Other crucial enablers for the future will be collaboration and access to real-time data.

The clinician survey respondents expected a variety of technologies to improve the efficiency and effectiveness of diagnosis in the next 3-5 years, with the most likely areas being telehealth (83 per cent), AI (75 per cent) and biosensors (74 percent). However, clinicians were much less likely to see cloud computing, quantum computing, blockchain and digital twins as technologies that will improve their performance. Over the next five years diagnostics companies are likely to introduce a range of technologies into their portfolios to improve the management and security of health data, such as cloud computing (96 per cent of companies) and AI (97 per cent). Moreover, blockchain, nanotechnology, virtual/augmented reality, quantum computing and digital twins are also likely to be introduced by over three-quarters of our surveyed companies during the next five years. This again demonstrates that the industry has a role to play in educating providers and payers about the benefits of these technologies.

New diagnostic pathways will be crucial drivers of the future of health

Crucial trends that will shape the future of diagnostics include widespread adoption of biosensors and a growth in the use of companion diagnostics; increased adoption of liquid biopsies and minimum residual disease monitoring; direct to consumer testing and automation; and the transformation of pathology and radiology using AI and advanced analytics. Furthermore, partnerships with consumer technology companies will help shape this future and help to transform future clinical pathways. Collaborations will also be essential in designing new value-based payment models that reward all partners for health outcomes and better management of prevention, early detection and wellness.

Conclusions and actions for stakeholders

Healthcare systems across Europe are in a period of transition, moving from largely reactive and episodic models of care that are increasingly costly and inefficient to operate, to predictive, preventative personalised and participatory (4P) care models that are enabled by innovative technologies and deliver better value for patients and the healthcare system. Disruptive technologies are also changing ways of working across the health ecosystem, helping to bridge the gap in workforce numbers and democratise access to healthcare. Big data, AI, mobile applications, 3D printing, cloud computing, advanced sensors and other technologies are creating new opportunities for diagnostic companies to integrate their products more effectively into care pathways. Interoperable electronic health records that enable the aggregation and integration of real-time data from a variety of sources can speed up diagnosis and allow healthcare institutions and practitioners to deliver more targeted, evidence-based medicine.

Diagnostics companies can capitalise on the opportunities arising from these changes to become insightful partners in clinical pathways, helping to deliver more patient centric, value-based care. These developments have the potential to transform the diagnostics industry, with ramifications across the value chain, affecting patients, providers, clinicians, scientists, laboratories and the biopharma industry. The future is one in which diagnostics are crucial drivers of the future of health but realising this future will require diagnostics companies to decide which role they want to play in the future of health, whether its as a commodity supplier, a best-in-class innovator, a service provider, a data and informatics provider or a consumer health enabler.

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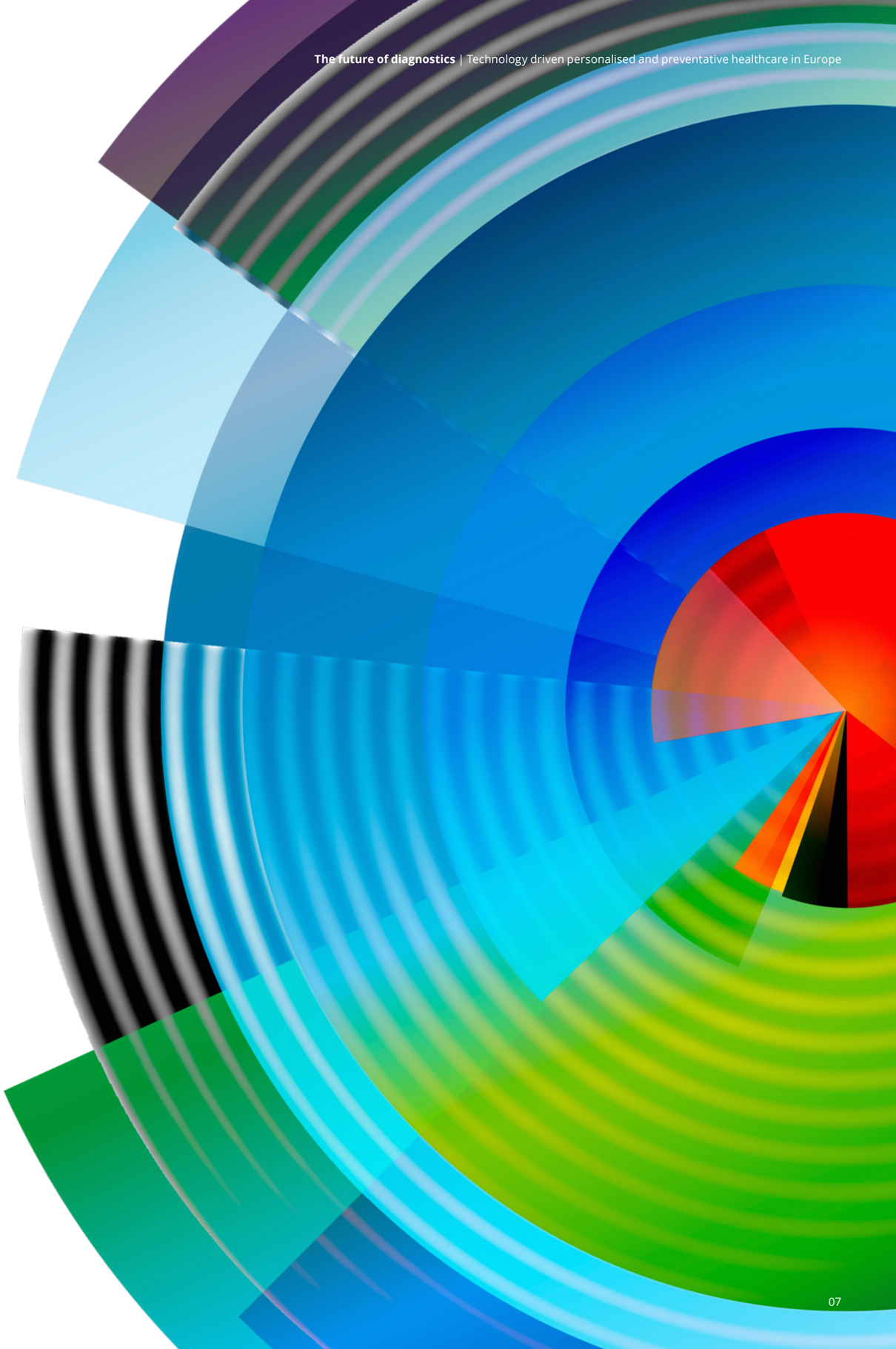


Key facts and trends

In 2020, the European medical technology industry directly employed over

760,000

people across more than 33,000 medical technology companies[1]

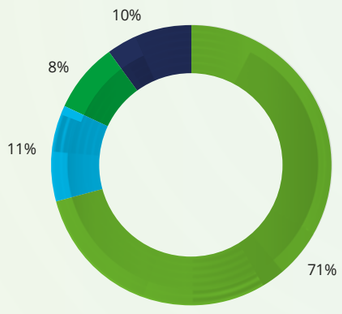
An estimated

€265 per person

is spent on medical technology in Europe, approximately 7.6 per cent of total healthcare spending. In vitro diagnostics comprise 0.8 per cent of this, and medical devices (including imaging) the remaining 6.9 per cent[2]

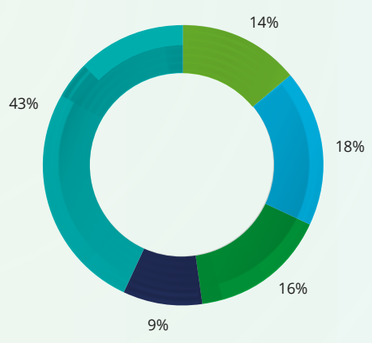
In vitro diagnostic (IVD) tests influence as many as 70 per cent of clinical decisions, but account for only 0.8 per cent of healthcare expenditure.[3] Although the three largest IVD manufacturers have a collective global market share of approximately 50 per cent, over 95 per cent of IVD companies are small and medium-size enterprises (SMEs).[4 5]

IN VITRO DIAGNOSTICS



- Estimated European market value over **€8.3 billion** in 2022 (global value €47 billion)
- CAGR between 2015-2030 is 2.9%
- Infectious disease diagnostics make up the largest share of the market

DIAGNOSTICS IMAGING



- Estimated European market value over **€6.5 billion** in 2022 (global value €27 billion)
- CAGR between 2015-2030 is 4.8%

Source: Global data medical database, accessed September 2022.

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Europe is the second largest diagnostic imaging market (behind the US) with a

29 per cent

global share. Germany has the largest portion of this market, followed by the UK and France.[6]

The top three diagnostic imaging companies based on market share represent nearly two-thirds of the global market. The top ten diagnostic imaging companies represent over

90 per cent

of the market.[7]

Access to imaging tests varies widely across Europe, with the total number of recorded CT, MRI and PET scanners varying from **15 to 76 per 1,000,000 population** across Europe and corresponding exams ranging from **121 to 349 per 1,000 population**.[8]

The size of the global connected medical devices market is expected to increase to over

$100 billion

by 2027, up from approximately $30 billion in 2021.[9]

The European market for software as a medical device is expected to reach

$24,900 million

by 2027, up from $5,430 million in 2019, a CAGR of 21.9 per cent between 2020 and 2027.[10]

Europe ranks second in the expected total number of 5G connections by 2025 (at **236 million**, behind China and Taiwan at **828 million**). This will increase the accuracy and speed of processing and enable the development of new digital diagnostics.[11]

About this report

This report explores the future of diagnostics in Europe. It examines how innovations are improving diagnosis and creating opportunities to transform the role of diagnostics in care pathways. It identifies the barriers that the industry is facing today, and how these might be overcome to realise improved health outcomes tomorrow.

Introduction and aims

Most other industries are adopting technology-enabled models of service provision and new ways of working, at an increasingly rapid pace. Healthcare, while traditionally slow to embrace innovation, has accelerated its adoption in the past few years. Diagnostics are an integral part of healthcare and present a clear opportunity to improve the cost-effectiveness of healthcare and support new ways of working.

There are a wide range of diagnostic devices and tests for investigating the presence or absence of a wide range of deficiencies, abnormalities and diseases (see Figure 1). They can provide a differential diagnosis and identify appropriate treatment and the need for further examination or referral. They can also help avoid unnecessary invasive procedures. Diagnostics are therefore crucial to almost every clinical interaction. Moreover, the importance of diagnostics is increasing due to the clinical imperative of obtaining earlier diagnosis to enable more precise and cost-effective response to the rising demands and increasing complexity of needs of a growing and ageing population. Diagnostics are also crucial for accelerating the move towards more predictive, preventative, personalised, participatory (4P) medicine.

For the purposes of this report our definition of a diagnostic device is any instrument, apparatus, appliance, software or digital product, implant, material, or other article intended by the manufacturer to be used, alone or in combination, for the diagnosis, prevention, monitoring, prediction or prognosis of disease, injury, or disability. In vitro diagnostic tests generate information from the examination of specimens obtained from the human body.

Our research aimed to:

- establish the challenges facing the diagnostics industry before the onset of the COVID-19 pandemic and how the pandemic accelerated changes to diagnostic pathways and technology adoption
- understand how new technologies and models of diagnostic service delivery designed around the patient to optimise outcomes will alter care pathways and result in a shift in the location of diagnostic services (across prevention, prediction, diagnosis and chronic condition monitoring)
- obtain a better understanding of the barriers that diagnostics companies face today in relation to regulation, funding and investment, workforce and skills, infrastructure, and supply chain considerations, to help identify solutions that can turn these barriers into enablers for the future of diagnostics
- predict how the future of health will be influenced by the changing role of diagnostics companies, aided by the development of new diagnostic technologies that feature improved interoperability and connectivity and enable the collection and collation of data to support new ways of working.

Our methodology

The findings in the report are derived from an extensive literature review, semi-structured interviews with 40 stakeholders from across the diagnostics ecosystem, a pan-European survey with responses from 250 companies with at least one diagnostic product in their portfolio, survey responses from 751 front-line clinical staff (clinicians) working in six European countries, and insights from Deloitte colleagues across the world. For full details of our methodology including country breakdowns and survey respondent demographics, please refer to Appendix 1.

Figure 1. The diagnostics industry comprises a wide range of imaging, in vitro, and digital technologies

* These include tests requiring lab analysis, point of care tests, self-testing and direct to consumer tests
** Other includes techniques such as ultrasound, endoscopy and mammography

Source: Deloitte analysis.

Why diagnostic services in Europe need to change

Models of diagnostic service delivery have remained largely unchanged in Europe for most of the past 50 years. Tests have traditionally been performed primarily in hospitals and centralised laboratories, usually following referral by a primary care practitioner or hospital specialist. At the same time, relentless increases in demand and pressures on capacity and resources have led to growing delays in accessing diagnostic services and obtaining test results. Advances in science and rapid technological innovation will provide part of the solution; however historically the adoption of diagnostic innovations has been slow. The COVID-19 pandemic added to delays but also accelerated the adoption of innovations, including shifting the location where diagnostic testing can occur, improving patient involvement, and highlighting the crucial role of diagnostic technologies in improving clinical outcomes.

Healthcare systems in Europe are diverse with variations in their approach, funding and outcomes

Healthcare systems in countries across Europe are diverse, the result of history, culture, and the economic and political climate in which they operate. They range from predominantly single payer systems as in the UK and Spain, which historically have tended to spend a lower proportion of General Domestic Product (GDP) on healthcare, to systems of competing insurers as in Germany and the Netherlands, traditionally, two of Europe's highest spenders on healthcare.[12]

There is a body of literature that explores variations in medical practices, both within and between European countries. For example, the Organisation for Economic Cooperation and Development (OECD) '*Health at a Glance*' series of annual reports compares health and health system performance across OECD member countries, including differences in life expectancy, health status, risk factors, health seeking behaviours, access, quality of care, and the financial and physical resources available for health.[13]

The OECD's analysis of diagnostics highlights their important role in medical diagnoses, and that investment in new diagnostics is a leading cause of increased health spending. It focuses on the availability and use of three diagnostic imaging technologies: computed tomography (CT), magnetic resonance imaging (MRI) and positron emission tomography (PET). It notes that there is no general guideline or international benchmark regarding the ideal number of CT scanners, PET scanners or MRI units. Too few units may lead to access problems in terms of geographical proximity or waiting times, while too many may result in overuse of these costly diagnostic procedures, with little if any benefit for patients. Its 2019 analysis shows wide variations across Europe in the number of scanners and examinations across each of the three imaging technologies:

- the combined numbers of the three imaging technologies are higher than the OECD average (45 per million population) in Greece, Germany, Italy, Iceland, Switzerland, Austria, Denmark and Finland (ranging from 48 to 76 scanners per million population) and much lower than average in Hungary and the UK (15 and 16 scanners per million population respectively)
- taken together, the OECD average use of scanners was 238 per 1,000 population but was highest in Austria, Iceland, France, Luxemburg and Germany (ranging from 349 to 292 exams per 1,000 population) and lowest in Finland, Poland, UK, Netherlands and Italy (ranging from 121 to 178 exams per 1,000 population).[14]

Prior to the pandemic, healthcare services faced a mismatch between demand and supply

Prior to the pandemic, most healthcare systems in Europe were facing relentless increases in demand, including demand for diagnostics, from a growing ageing population with complex health conditions. This growing demand was putting increasing pressure on the healthcare system due to shortages of health staff and bed capacity in hospitals. An OECD study in 2019 found that this mismatch between demand and supply had led to waiting times becoming a high or medium-high priority issue in most European countries (except Germany and Switzerland). The main concern was about waiting times for elective (non-urgent) treatments and for specialist consultations, but in over half of the countries in the study, there were growing concerns about waiting times for primary care/general practitioner consultations, hospital emergency department visits, and access to diagnostic tests. There were also concerns about the harm caused by delays in diagnosis and treatments in the areas of cancer care, cardiac care and mental health services.[15]

The OECD report concluded that there was no 'one-size-fits-all' solution and that approaches tended to combine setting a target for or commitment to maximum waiting times, together with supply-side and demand-side interventions, with regular monitoring of progress. However, most interventions were short-term additional investments that generally failed to improve patient backlogs, suggesting that long-term improvements were needed, such as improved service management, increases in workforce numbers, new technology-enabled ways of working, and new payment models. Improving referral systems, including the use of diagnostics gatekeepers, was seen in the report as a potential way of tackling the growing diagnostics backlogs.[16]

In addition to the problem of backlogs and the harm caused to patients by delays, there is also evidence of waste and harm caused by missed or wrong diagnoses.[17] Extensive international research estimates that around one in ten people in developed countries suffer avoidable harm caused by a range of errors or adverse events while receiving healthcare; and that missed or wrong diagnoses are a major reason for avoidable errors.[18] Research conducted in the US in 2019 found that 34 per cent of errors resulting in death or permanent disability stemmed from an inaccurate or delayed diagnosis, making diagnostic error the number one cause of serious harm from medical errors.[19] There is therefore a need to improve the availability, speed, and accuracy of diagnosis, in terms of both the reliability of the technology and also the clinical interpretation of test results.

In England, an independent review of diagnostic services, *Diagnostics: Recovery and Renewal*, (October 2020) found that demand and activity had been increasing year-on year, across all aspects of diagnostics, including imaging, pathology, endoscopy and genomics. This had led to increasing waiting times, and backlogs in reporting. The review considered that diagnostic services had been approaching a tipping point before the pandemic which had been exacerbated in areas, such as imaging and routine tests, during the pandemic. It recommended substantial reforms and investment to improve diagnostics provision, including new virtual and community pathways, new technologies, increasing the size of the workforce and digitalisation.[20]

The crucial role of diagnostics in responding to the COVID-19 pandemic

The COVID-19 pandemic has devastated most countries. The reporting of over 600 million cases and over 6.5 million deaths by September 2022 is likely to be an underestimate as many cases went undetected and deaths unreported. Millions of survivors are suffering from long-lasting symptoms that prevent a return to normal life, and mental distress has increased substantially. There has also been a clear social gradient to the risk of infection and death from the virus, which continues to be extremely challenging for healthcare systems globally.

The pandemic highlighted the importance and advantages of organisations and countries having sufficient resources to be able to respond in a timely and agile manner. It exposed those countries that were less prepared or whose resources were already over-stretched. Substantial investments were made in many countries to improve the health infrastructure and changes were made to regulations to enable more timely sharing of health data.

"Genomics in the pandemic has been critical and at the core of our response. Without it I doubt we would have the vaccine yet" -

Sequencing technology company

Massive funding was deployed to develop new diagnostic tests and fast-track the development of effective vaccines and treatments.[21] Genomic sequencing to identify new variants of the SARs-CoV-2 virus and to test the effectiveness of potential treatments helped raise the profile of genomics in improving the accuracy of diagnostics.

The importance of access to routine diagnostics was challenging during the pandemic. In most European countries, routine diagnostic services such as screening and tests to support elective operations were halted: this added significantly to existing backlogs and for many patients delayed obtaining diagnosis.

Significant delays in cancer diagnosis and access to diagnostic services were reported in many European countries, including, Belgium, Denmark, Finland, France, Ireland, Italy, the Netherlands, Sweden and the UK. The consequences of these delays are only now being seen.[22]

Governments across Europe have acknowledged the vital role of diagnostics in shaping more efficient and effective models of patient care, and that new types of diagnostics and diagnostic service delivery models are needed to help increase service capacity and improve experience and outcomes for patients. Case study 1, on the UK Government's *Delivery plan for tackling the COVID-19 backlog of elective care* (February 2022) summarises how the UK government aims to tackle the COVID-19 backlog and reduce diagnostic waiting times.[23]

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Case study 1. The UK government's *Delivery plan for tackling the COVID-19 backlog of elective care*

Situation

The COVID-19 pandemic had a significant impact on the delivery of elective care in the UK. The NHS gave priority to urgent and COVID-19 treatments, and elective care and treatment of outpatients were substantially reduced. As a result elective care backlogs and the backlog for routine diagnostic services grew. Backlogs are having a disproportionate effect on people in more deprived areas, with a waiting list increase of 50 per cent in the poorest areas and compared to 35 per cent in the richest.[24]

There is a clinical consensus that fast and timely diagnosis is a critical element for many elective care pathways. In 2004, in response to concerns about increasing delays in obtaining a diagnosis and treatment, the NHS Improvement Plan set out a target that by March 2008, waiting times for a diagnostic test should not exceed six weeks. Implementation of this plan steadily reduced the numbers of patients waiting more than six weeks and between 2008 and 2013 the target was met by most providers.[25] However since November 2013 the target has been missed and waiting times have increased year-on-year. In April 2020, there was a sharp increase in waiting times at the start of the pandemic, from which the NHS has yet to recover.[26] Consequently in February 2022, the UK government published a '*Delivery plan for tackling the COVID-19 backlog of elective care'*. This acknowledges the magnitude of the problem and outlines plans to reduce diagnostic waiting times, prioritising diagnosis for those with the most urgent need.[27]

Proposed actions

The delivery plan includes a target to reduce the waiting time for a diagnostic test to six weeks or less for 95 per cent of patients by 2025 and accelerating cancer diagnosis.[28] It proposes four key areas to tackle the diagnostic backlog:

- **Increasing health service capacity** by increasing access to diagnostics, increasing the capacity of the clinician's workforce through recruitment and technology, strengthening the relationship with independent sector providers, and separating elective from urgent services
- **Prioritising diagnosis and treatment** and reducing waiting times by improving national frameworks for diagnosis and treatment to better prioritise patients and offering alternative locations
- **Transforming elective care provision** by increasing flexibility for the patient, improving convenience of and access to diagnostics via community diagnostic centres and performing more tests simultaneously
- **Providing better information to support patients** and increasing the use of digital technologies for information sharing and appointment management and providing greater patient support and feedback mechanisms.

Ultimately, this strategy aims to transform access to diagnostic services so that they are more convenient for patients, using data and digital tools to support the delivery of diagnostic services and optimise elective care.

"During the pandemic we introduced COVID-19 testing within around six weeks and every patient had access to a test. If we look at antibody testing, we got it down to 3-4 days from the test being on the market to adoption – leadership was what was different about that. We learned that it's not about money, it's about the prioritisation of an organisation to do the work."

Industry body

The pandemic has expedited the development and adoption of innovative diagnostic technologies

Over the past 25 years, the medical imaging industry has undergone tremendous change: moving from analogue to digital systems; from invasive to non-invasive imaging; and from pixelated, black-and-white, two-dimensional images to colour-rich, three-dimensional imaging. There has been an opportunity to shift from hospital-based imaging services to a mixed model of hospital and community imaging. More recently, innovative diagnostic technologies, aided by advances in computing power, connectivity, and miniaturisation, are transforming imaging and most other diagnostic services more radically, including where diagnostics takes place. However, adoption of these innovations has been slow and rarely at scale. Even so, the pandemic, by acting as a catalyst for the development and adoption of innovation across the healthcare system, in particular it has expedited the future of diagnostics. For example, it has:

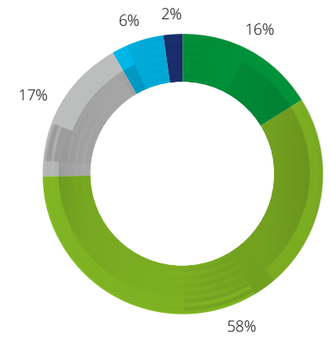
- expedited adoption of innovations in CT, MRI, ultrasound and other imaging technologies, with imaging systems becoming smaller and more mobile, and AI applications improving the speed and accuracy of results
- prompted the rapid development and widespread adoption of IVD technologies to detect the SARS-CoV-2 viral infection, with 'lateral flow' tests and 'PCR' (polymerase chain reaction) tests becoming household names and the number and capacity of pathology laboratories expanding to meet the exponential increase in demand
- heralded the widespread adoption of digital diagnostics, specifically telehealth technologies such as at-home vitals-sign remote patient monitoring, and virtual primary care and outpatient consultations
- increased the adoption of point-of-care (PoC) IVD tests, evidenced by a predicted increase in the value of European PoC IVD market value at a CAGR of 9.7 per cent between 2022 and 2027[29]
- increased the use of at home self-testing and self-sampling, mainly for COVID-19 tests, but increasingly for self-sampling bodily fluids and with lateral flow tests for other infectious diseases, and remote monitoring devices for chronic conditions such as continuous blood glucose monitors
- expanded community testing (in England £350 million has been invested in establishing 40 community diagnostic centres aimed at providing greater access to MRI, CT, and ultrasound services, as recommended by the independent 'Review of Diagnostics Capacity)[30] [31]
- harnessed the potential of advanced genomic sequencing to develop more preventative and personalised approaches to care.

Much of this innovation, especially in developing new tests and treatments for COVID-19, was made possible through collaboration between governments, academia, regulators, and diagnostic companies, and with government funding of the search for, and widescale adoption of, mass testing technologies. These collaborative partnerships have also encouraged private equity and venture capital funding of other innovative diagnostic tests. Ultimately, a new diagnostic infrastructure and new models of care delivery have begun to emerge across Europe.

Most diagnostics companies have experienced increased adoption of their devices

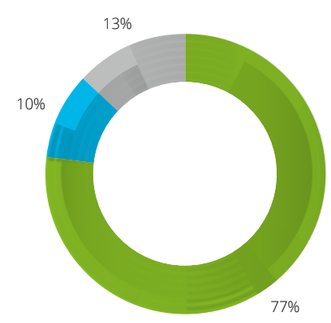
In response to our survey, 74 per cent of diagnostics companies across Europe said that since the onset of the pandemic there had been an increase in adoption of their diagnostics, compared to only eight per cent of respondents who said it had decreased (see Figure 2). This increase occurred across a wide spectrum of device categories, from imaging to IVDs and digital products. Greater priority is therefore now being given to diagnostics, and healthcare systems are investing to improve their diagnostic capacity and reduce backlogs. The pandemic has also led to an ongoing shift in the location of where diagnostic tests are carried out: 77 per cent of industry respondents reported that their products are already part of this shift and 13 per cent that they could be.

Figure 2. The pandemic has increased the adoption of diagnostic technologies and shifted the location of diagnostics



Question: To what extent has the pandemic changed the adoption of diagnostic?

- Increased to a great extent
- Increased somewhat
- No impact
- Decreased somewhat
- Decreased to a great extent



Question: Are your products part of the shift in moving diagnostics out of the hospital?

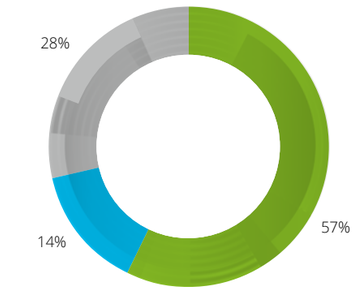
- Yes
- No
- They could be, but are not currently

The diagnostic industry believe the pandemic has increased the adoption of diagnostic technologies and also shifted diagnostics out of the hospital, over three quarters of the survey respondents have products that are part of the shift in moving diagnostics out of hospital.

Source: Deloitte analysis of iResearch survey of 250 MedTech companies.

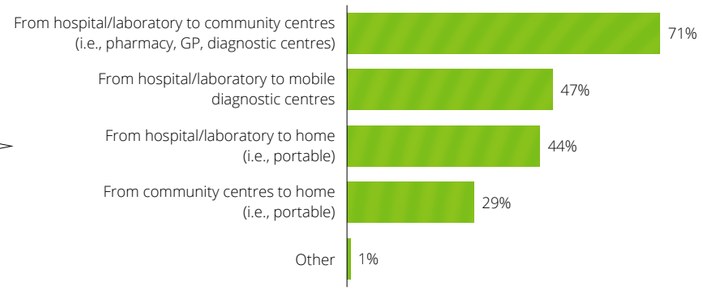
Figure 3. Clinicians are seeing a notable shift in the location of diagnostic services

Research suggests there is a shift in location of where diagnostic services are taking place. Would you agree with this?



Respondents who said 'Yes'

What shift in location of diagnostic services are you seeing?



Note: Multiple answers permitted.

Source: Deloitte draft analysis of Sermo survey of 751 clinicians: Question: Research suggests there is a shift in location of where diagnostic services are taking place. Would you agree with this? If yes, what shift are you seeing?

"The pandemic has opened the doors to testing in decentralised ways as a much more efficient way of giving people their test."

Global diagnostics company

"The pandemic has resulted in an acceleration of decentralised care. There were a lot of fears around this before and COVID demonstrated that is it possible to have home and pharmacy tests and the results are correct. People can do self-sampling for example. The pandemic has accelerated what we were expecting by 5-10 years."

Multinational biotechnology company

The pandemic has expedited a shift in where diagnostic testing takes place

Furthermore, 57 per cent of the clinicians that responded to our survey said they were seeing a shift in where diagnostics takes place, with 71 per cent highlighting the move from hospitals and centralised laboratories into community centres, GPs, pharmacies, and diagnostic centres (see Figure 3).

Figure 4. The key drivers influencing the shift in where diagnosis takes place

Diagnostics company survey respondents	Clinician survey respondents
1. Improved access and convenience for patients/ consumers – 46% (16%)	1. Improved convenience for patients/consumers – 25% (9%)
2. Improved efficiency of diagnostics – 45% (14%)	2. Reducing the demand on secondary care settings – 25% (9%)
3. Improved effectiveness of diagnostics – 44% (17%)	3. Obtaining earlier diagnosis – 25% (8%)
4. Proactive preventative care through targeting specific population groups – 40% (12%)	4. Improved access for patients/consumers (i.e., physical access and improved parking options) – 21% (8%)
5. Providing earlier diagnosis – 38% (14%)	5. Improved effectiveness of diagnostics – 17% (5%)
6. Improved economy of diagnostics – 32% (11%)	6. Proactive preventative care through being able to target specific population groups – 17% (5%)
7. Reducing the demand on secondary care settings (such as tackling waiting lists) – 31% (8%)	7. Improved efficiency of diagnostics – 15% (5%)
8. Payers' willingness to pay for alternative locations – 25% (8%)	8. Improved cost of diagnostics – 15% (5%)
	9. Improved funding for alternative locations of diagnosis – 12% (5%)
	10. Other – 4%

Note: The main percentage figure is a combined figure representing percentage of respondents who chose the answer as one of their top three challenges; the figure in brackets is the percentage choosing the answer of their top challenge.

Source: Deloitte analysis of iResearch survey of 250 diagnostic companies and Sermo survey of 751 clinicians. Q. What do you see as the top three key drivers influencing the shift in location of diagnostic services (select top three and rank 1-3)?

Both our industry and clinician respondents agreed that the main reason for the shift in location is to improve access and convenience for patients. However, whereas diagnostic companies also thought that it was to improve the efficiency and effectiveness of diagnosis, clinicians believed it was to reduce demand on secondary care settings and obtain earlier diagnosis (see Figure 4). Companies developing new diagnostic technologies should therefore consider how to design their devices for use in non-traditional locations, and bear in mind the expectations of clinicians in supporting this shift in location and the opportunities to collaborate to develop new care pathways.

However, our interviewees from across the diagnostics ecosystem pointed out that current home-based and point-of-care IVD tests do not yet compete with the quality of gold standard laboratory technologies such as PCR tests. Despite uncertainty around the continued use of at-home lateral flow tests which are perceived to be less reliable, the pandemic has demonstrated to industry leaders that the public are able to self-sample on a large scale, whether it's stool sampling to test for bowel cancer that some countries have conducted for several years, or the recent FDA-approved cervical screening home test.

"There is a real demand out there now because people are used to doing a convenient diagnostic test and getting a result without GP intervention, and not having to book an appointment to get the result. That is the change and we need to make sure the industry responds to it."

National diagnostic laboratory

There is now an increased expectation of easier and more convenient diagnostic tests

The pandemic has given rise to greater levels of patient activation and confidence in self-monitoring and self-testing heralding a desire for a more proactive rather than reactive approach to prevention and treatment. Research suggests that such patient activation is associated with improved health outcomes and lower long-term financial costs.[32] Moreover, our survey of clinicians across Europe found that 57 per cent of respondents were seeing an increase in patient's levels of engagement with their health with increase in engagement highest in Ireland.

"We need to make diagnostic solutions as accessible as possible and have it fit in with patients' lifestyles."

Diagnostics company

Direct-to-consumer testing

The rise of patient-consumerism has turned the concept of diagnostic testing on its head, with patients increasingly adopting a self-service healthcare mentality and the popularity of direct-to-consumer (DTC) testing has increased five-fold. This has enabled traditional diagnostics companies to expand their services and new entrants, particularly digital health companies, have entered the DTC market. Market research indicates that Europe has the second largest share of the global DTC testing market, which is predicted to grow from $1.2 billion in 2019 to over $5 billion in 2027.[33] The growing popularity of the DTC market is driven by factors such as convenience, privacy, cost savings, self-empowerment, rapid turn-around times, and early disease detection.

Pre-COVID, genetic testing (provided by companies such as 23andMe) was at the forefront of DTC testing.[34] Today, consumers can access a myriad of DTC genetic and other types of at home testing kits to determine general wellness, food or allergen sensitivities, and tests for sexually transmitted diseases and other infections. Case study 2 describes a direct-to-consumer blood testing service, Medichecks, which exemplifies a partnership between industry and healthcare to drivethe deployment of a remote testing service during the pandemic. Medichecks provide an increasing library of at home tests for health monitoring, requiring only a finger prick blood sample. Current tests range from advanced thyroid function blood tests to various vitamin and hormone tests.

Case study 2. Medichecks created the UK's first direct to consumer blood testing service

Situation

Aiming to empower citizens to manage their own health, Medichecks created the UK's first direct to consumer blood testing service.[35] Further to this, during the pandemic Medichecks broadened their portfolio, being among the first companies to release a COVID-19 antibody test, offering further tests to support remote GP services and piloting remote blood test services within the NHS.[36]

Action

Medichecks aim to simplify home blood testing and provide a wide range of laboratory tests with user-friendly results and actionable advice from qualified medical professionals. Furthermore, their accredited testing laboratories are trusted by both the NHS and private clinics in the UK, aiming to remove the need for any repeat testing by healthcare professionals.[37] With tests for testosterone and fertility starting at £35, Medicheck's extensive range of over 250 tests (tracking a total of 450 biomarkers) covers the main areas of women's and men's health, sports performance, fertility, thyroid, and hormones.[38] [39] This wide range of tests offers value to a broad customer base, with the convenience of finger-prick at-home testing in addition to venous testing at a local clinic (of which there are more than 200 across the UK). Health and lifestyle advice is additionally provided via their "Health Hub", further empowering customers by providing relevant health and wellbeing information.

Outcome

Currently over seven million online test results have been provided by Medichecks to customers over a period of 20 years.[40] Furthermore, Medichecks leveraged their market position to conduct the 'Great British Health Check' in December 2021: a survey of 1,302 individuals and analysis of 827,767 existing datasets collated from over two years of blood testing, to understand the consumer's current state of health.[41] In addition to revealing that 77 per cent of individuals' attitudes towards their health had shifted within the past two years, this research revealed that more than one in three people are now taking more responsibility for their health.

Across Europe, DTC tests for general wellness purposes have in the past not required regulatory review, but digitally enabled DTC tests that provide a medical diagnosis now come under the European IVD Regulations (from May 2022) and medical device regulations (from 2021). Companies therefore need find a suitable balance between rapid technological development and the deliberative and cautious nature of the new regulations, and the risks will need to be carefully assessed by regulators, clinicians, and researchers to optimise benefits and minimise harm to the public. However, many DTC tests currently have varying levels of evidence that support their claims, something that diagnostics companies will need to address to comply with theregulations.

The step-change in DTC testing is likely to transform pathology screening services, improve the comfort and convenience for patients and increase patient involvement in their own health. However, only 41 per cent of the clinicians in our survey say they use data from DTC tests regularly, compared to 91 per cent who use IVDs regularly and 82 per cent who rely on diagnostic imaging. Although a shift in the location of diagnostic services can benefit patients and healthcare systems, there is a need to ensure that the results can be readily uploaded into patient records. There will also still be a need for fast and reliable diagnostic tests in emergency settings (including POC tests), where an urgent response is required on receipt of a positive test result. At some time in the future, advanced technologies that compete with current 'gold standard' diagnostic tests are likely to emerge that enhance the delivery of diagnostic services both within and outside traditional settings.

The current position of diagnostics in Europe

Accelerated by the pandemic, diagnostic pathways across Europe are evolving to meet demand and the needs of both patients and service users. Currently however clinicians experience a variety of challenges in being able to obtain a timely diagnosis.

The main challenges identified by our survey of clinicians were delays in patients being able to access a clinician (43 per cent selected this response as one of their top three challenges), slow test turn-around-times (39 per cent), delays due to the pandemic-related backlog (35 per cent), and a lack of diagnostic testing facilities near the patient (33 per cent), see Figure 5.

Figure 5. Clinicians' views of the top three barriers to obtaining a timely diagnosis

Clinician survey respondents
1. **Delays in patients being able to access clinicians – 43% (16%)**
2. **Diagnostic test throughput/ turn-around-time – 39% (14%)**
3. **COVID-19 pandemic related backlog– 35% (11%)**
4. A lack of diagnostics near the patient for example, at home or in the community – 33% (11%)
5. Not enough laboratory/imaging staffing available – 30% (9%)
6. Delays in clinician referral for a diagnostic test – 29% (9%)
7. Financial cost of performing the diagnostic test – 27% (8%)
8. Not enough diagnostic equipment available – 25% (8%)
9. Communication and data interoperability barriers between clinical functions – 20% (6%)
10. Lack of trust in at-home diagnostics – 12% (4%)
11. Cyber security concerns – 8% (2%)
12. Other (please specify) – 1% (0%)

Note: The percentage of respondent reflects the numbers ranking the product as one of their top 3 challenges; the figure in brackets is the percentage choosing as the top challenge.

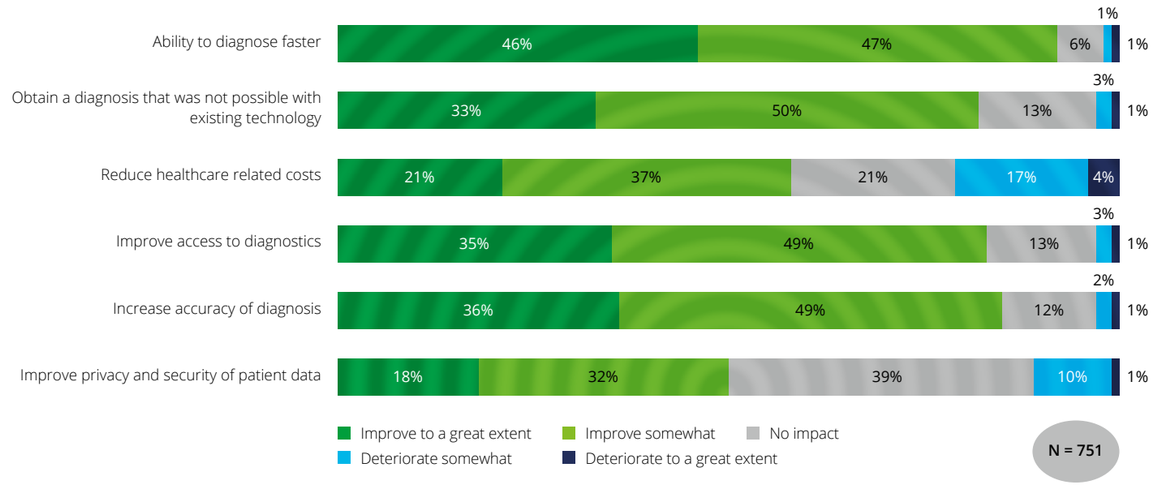
Source: Deloitte analysis of Sermo survey of 751 clinicians. Q: What are the current barriers in obtaining a timely diagnosis?

Note: Multiple choice questions; percentage represents proportion of total respondents selecting a particular option as one of the top three barriers.

Importantly, clinician respondents were very positive about the impact of new technologies: 93 per cent consider that adopting new diagnostic technologies will improve their ability to diagnose faster; and 83 per cent say that they will be able to obtain a diagnosis that isn't possible with existing technology (see Figure 6). However, respondents were mostly negative about the impact on costs, with a fifth believing that costs will increase due to adopting new technologies.

It is clear is that there are many types of innovations already available that can diagnose patients earlier and get them more precise treatments but, as yet, these have not been adopted at scale. There is irrefutable evidence that when adopted and embedded into everyday use, diagnostics can alleviate pressure on clinicians and save resources. However, there remains a considerable gap between the value that diagnostic tests can offer, and the funding available for them.[42]

Figure 6. The extent to which new technologies can help improve patient outcomes



Source: Deloitte analysis of Sermo survey of 751 clinicians. Question To what extent do you think adopting new diagnostic technologies will improve patient outcomes in the following areas?

The challenges in product development and adoption

Diagnostics companies face many challenges in product development and in scaling up adoption and growing their markets in Europe. Our research sought to understand what the challenges are, how the industry is responding and how concerns about the digital infrastructure, interoperability connectivity, and attitudes to digitalisation are being addressed. It also explored the characteristics of innovative products that would improve adoption and scale of use, and how sustainability goals were affecting diagnostics.

The challenges in bringing a new innovative product to market

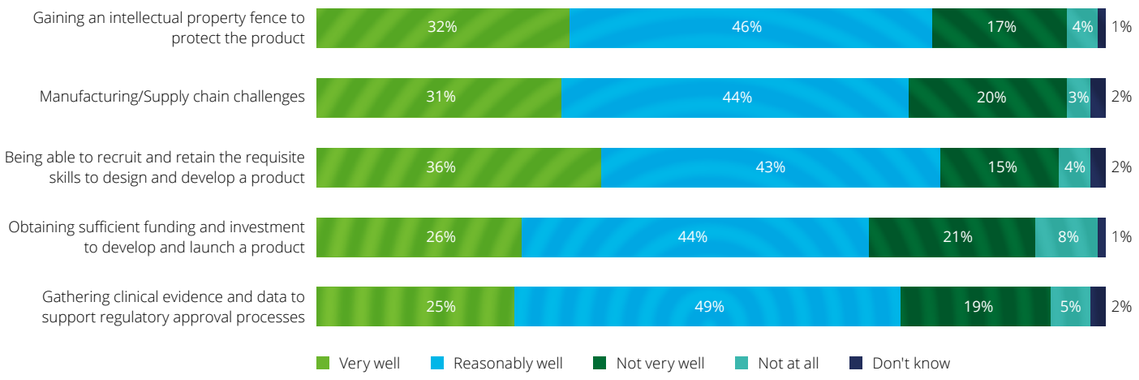
The first step in developing a new product is to identify an innovation that would fill a gap or meet a need in the market. This means developing a clear understanding of what consumers, clinicians and providers need and, importantly, would be willing to pay for. Most diagnostic companies told us that they were 'well' or 'reasonably well' prepared to deal with the challenges in developing innovative products, particularly in obtaining intellectual property (IP) protection and in recruiting and retaining people with the requisite skills to design and develop a product.

Companies felt least prepared in being able to obtain sufficient funding and investment to develop and launch a product and in gathering enough clinical evidence to support the regulatory approval process (see Figure 7).

Many of our interviewees from the industry agreed that obtaining both funding and sufficient clinical evidence were real challenges, especially for companies competing to develop new IVDs and digital diagnostic technologies. They considered that this was due largely to the high number of small or medium-size companies in this innovation space and the risk-averse attitudes of payers to adopting new technologies.

However, our interviewees also noted that funding was less of an issue in the imaging market, given that most imaging companies are large multinationals that are more capable of embracing change. However, they also thought that the next decade is likely to bring more rapid and innovative transformation in imaging based on cutting-edge computerisation and AI technologies, and that payers may be less able or less willing to pay for the innovations without evidence from clear cost-benefit analyses.

Figure 7. The preparedness of diagnostics companies in dealing with challenges in developing innovative products



Source: Deloitte analysis of iResearch survey responses from 250 diagnostic companies. Question: How well prepared do you consider your organisation is at dealing with the following challenges in developing innovative products?

The top challenges faced during product development

We asked our survey respondents what they considered to be the top three challenges in bringing a new diagnostic product to market (see Figure 8). The digital infrastructure in healthcare (such as interoperability and connectivity) emerged as the biggest challenge, but over 40 per cent ranked healthcare cultures and attitudes and the regulatory process in the top three. Being able to provide sufficient evidence about the safety and security of products and being able to integrate a product into clinical pathways were also obstacles to bringing a product to market.

Figure 8. The main challenges diagnostics companies face in bringing a new diagnostic product to market?

Diagnostics company survey respondents
1. **Digital infrastructure in healthcare (e.g. data interoperability) – 51% (22%)**
2. **Healthcare culture/attitudes to technology enabled digital transformation – 44% (16%)**
3. **The regulatory approval processes – 40% (12%)**
4. Providing evidence-based assurance about the safety and security of the device (security by design) – 38% (12%)
5. Being able to integrate the device into clinical pathways – 36% (12%)
6. Demonstrating the cost benefit of the device to payer – 36% (11%)
7. Identifying an effective price/reimbursement – 34% (10%)
8. Competitor Landscape – 23% (6%)

Note: The percentage of respondent reflects the numbers ranking the product as one of their top 3 challenges; the figure in brackets is the percentage choosing as the top challenge.

Source: Deloitte analysis of iResearch survey of 250 diagnostics companies.
Note: Multiple choice questions; percentage represents proportion of total respondents selecting a particular option as one of the top three challenges.

"IVDs really struggle to get investment and in their ability to articulate the return on investment. If we look at imaging, new modalities are well understood, and yes it's expensive but it's a drop in drop out process for these devices."

Medical Technology Company

"Going forward, top of mind is the IVDR regulation – the higher hurdles for obtaining the CE mark and our ability to get authorisations. This is a concern for any new products."

Global medical technology company

"In terms of barriers, the number one thing that stands out is the level of rigidity and inertia that you see in diagnostic pathways."

Global diagnostics company

The main challenges in growing and maintaining the market for diagnostics

To understand the obstacles to growing and maintaining a market for new diagnostic products, we asked the diagnostics companies in our survey what they saw as the top three challenges in growing their market, and we asked our clinician respondents what they saw as the top three challenges in adopting new technologies (see Figure 9).

Sixty per cent of clinicians put costs as their top challenge while 40 per cent of company responents put culture and attitudes of healthcare providers and clinicians and their reluctance to accept results from wearables and at home diagnostics as their top challenge. The inadequate digital infrastructure in healthcare was the second biggest challenge for both diagnostic companies and clinicians.

Figure 9. The challenges faced in being able to grow and maintain the market for a diagnostic

What are the top three challenges you face in maintaining/growing the market for your product?

Diagnostics company survey respondents

1. **Healthcare providers culture/attitudes to accepting results from wearable/at-home diagnostics – 40% (16%)**
2. **Digital infrastructure in healthcare (such as data interoperability) – 37% (10%)**
3. **Providing evidence-based assurance about the safety and security of the device (security by design) – 36% (13%)**
4. Demonstrating the cost benefit of the device to payers – 32% (10%)
5. Identifying an effective price/reimbursement – 30% (10%)
6. Manufacturing/supply chain challenges affecting ability to meet demand – 29% (9%)
7. Being able to integrate the device into clinical pathways – 29% (8%)
8. The regulatory approval processes – 25% (6%)
9. Competitor landscape – 22% (11%)
10. Losing intellectual property on product – 20% (6%)

What are the top three challenges faced in adopting a new diagnostic technology?

Clinician survey respondents

1. **Cost of the device/technology – 60% (31%)**
2. **Digital infrastructure in healthcare – 39% (14%)**
3. **Workforce skills – 32% (7%)**
4. Willingness to working differently – 31% (9%)
5. Evidence on the benefit of the device – 31% (9%)
6. Lack of awareness of the device – 30% (10%)
7. Difficulty integrating into clinical pathway – 28% (8%)
8. Access to relevant training – 24% (6%)
9. Having trust in device safety and security – 24% (5%)

Source: Deloitte analysis of iResearch survey of 250 diagnostics companies and Sermo survey of 751 clinicians. Note: Multiple choice questions; percentage represents proportion of total respondents selecting a particular option as one of the top three challenges. The figure in brackets is the percentage choosing as the top challenge.

"Europe is a complicated market, it is still a patchwork of countries and regulations."

Multinational biotechnology company

The third biggest challenge for companies (36 per cent) however was in being able to provide evidence-based assurance about the safety and security of a device. Yet, having a robust evidence base would help companies demonstrate the long-term benefits and value added of their new technologies and by providing assurance on the return on investment (ROI) could address the main concerns of clinicians about costs. It would also help address clinicians' fifth ranked challenge on lack of evidence of benefits. Nevertheless, 32 per cent of diagnostics companies identified the time and costs involved in building an evidence base as one of their top challenges; something that clearly needs to be addressed is products are to be adopted at scale.

Importantly, 32 per cent of clinician respondents told us that the limited digital skills of their workforce are an important barrier to adoption of new devices. Our interviewees agreed that this was a problem and suggested that this points to a need for diagnostic companies to provide more effective education, training and support in the use of their technologies.

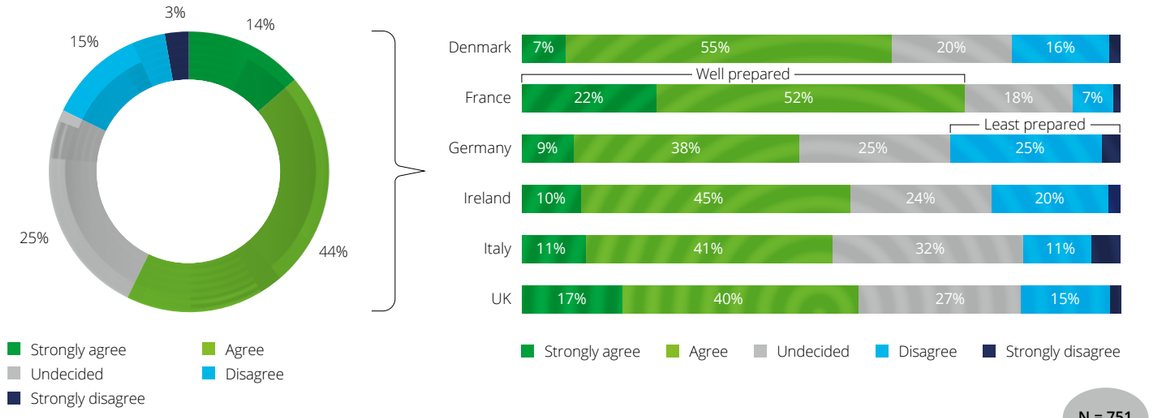
Our interviewees highlighted that diagnostic companies often face difficulties in integrating their technology into clinical pathways. While just under a third of clinicians and diagnostic companies agreed that this was an issue, a similar number of clinicians also mentioned a lack of willingness to work differently.

Our survey of clinicians found that the preparedness of healthcare systems to adopt new diagnostic technologies varies by geography with France the most prepared and Germany the least prepared (see Figure 10). This finding is consistent with our 2020 study *Digital transformation: Shaping the future of European healthcare,* which found Germany to be the least prepared for adopting digital technologies.[43] Our interviewees supported these findings on the different levels of preparedness: healthcare in Europe is a complex system, with individual countries each having their own unique requirements for adoption and reimbursement.

Figure 10. Clinicians preparedness to adopt innovative diagnostic technologies

The preparedness of healthcare systems to adopt new diagnostic technologies varies by geography, with Germany the least prepared of the healthcare systems surveyed, despite hosting the largest number of MedTech companies in Europe.

Extent to which clinicians agreed that their healthcare system is well prepared to adopt new diagnostic technologies



Source: Deloitte draft analysis of Sermo survey of 751 clinicians.

"Many companies struggle after product launch because they don't get paid - a challenge that many organisations have. Europe is complex: the German market is different to the French and Italian markets. Companies often underestimate the challenge of the reimbursement structure being completely different in Europe. Having a shared regulatory process doesn't mean you get paid: you have to go into every country with its own policy, reimbursement process etc… getting paid can take many years."

IVD company

"In the past universities and diagnostics companies have developed products that were of limited clinical use because they failed to address local or national priorities. A consequence is that adoption is slow due to the lack of clinical application. In the future diagnostics clinicians working with academia and industry, co-developing products is essential to speed up adoption."

Clinical Diagnostic Service

"Companies don't really have a good signalling system from the healthcare system into what they need/ require: we need demand signalling. COVID is a really good example of how when there is a clear signal of what healthcare needs industry can gear up and do it."

Life Science Policy and Market Access Expert

It is important for diagnostics companies to develop an understanding of the expectations and needs of clinicians in the different markets (as well as patients needs) when developing new technologies.

Interestingly, when asked to rank from one to five the importance of characteristics for new diagnostic tests or devices, diagnostic companies ranked reliability, ease of use and costs as the top three most important characteristics. Clinicians who were asked a slightly different question, namely, to rate the top three characteristics they look for when adopting a new technology: their rankings mirrored those of the diagnostics companies (see Figure 11). Below the top three there was a slight divergence in the importance given to other characteristics: rapid turnaround times were seen by clinicians as a higher priority compared to companies (4th versus 7th respectively) and cyber security/ security by design was ranked higher by companies compared to clinicians (6th versus 8th respectively). Overall, these findings suggest that the views of companies and clinicians may be reasonably well aligned, however, our interviewees noted that there is still a need for healthcare to devise a better way of signalling to industry what their priority needs are.

Collaboration through partnerships and joint ventures enable all stakeholders to improve their understanding of patient needs and deliver better and cost-effective care. Collaborations can also help ensure the effective transmission, aggregation, analysis, and management of data from connected devices, and support the move to 4P care.

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Figure 11. The relative importance of the main characteristics for innovative diagnostic products

Diagnostics company survey respondents	Clinician survey respondents
1. Reliability (4.21)	1. Reliability – 53% (23%)
2. Ease of use (4.13)	2. Ease of use – 46% (15%)
3. Cost (4.10)	3. Cost – 45% (16%)
4. Ease of result interpretation (4.04)	4. Rapid turn-around-time/throughput – 39% (11%)
5. Digital connectivity (4.03)	5. Ease of result interpretation – 33% (9%)
6. Cyber security/security by design (3.98)	6. Digital connectivity – 23% (7%)
7. Rapid turn-around-time/throughput (3.87)	7. Interoperability with other tests and medical data – 22% (7%)
8. Interoperability with other tests and medical data (3.87)	8. Cyber security/security by design – 16% (4%)
9. Environmental impact (3.80)	9. Portability – 14% (4%)
10. Potability (3.75)	10. Environmental impact – 10% (3%)

Question: How would you rate the importance of the below characteristics for new diagnostic tests/devices? (Not important at all (1), little importance (2), average importance (3), very important (4), absolutely essential (5)). Figure shown in brackets is the average score for each requirement.

Question: What are the top three most important characteristics of a test/ device when adopting new diagnostic technologies in future? Note: Multiple choice questions; percentage represents proportion of total respondents selecting a particular option as one of the top three challenges. The figure in brackets is the percentage choosing as the top challenge.

Source: Deloitte analysis of iResearch survey of 250 diagnostics companies and Sermo survey of 751 clinicians.

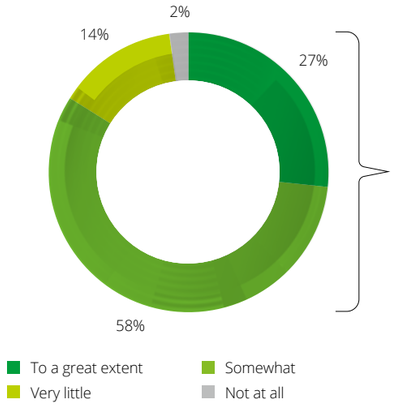
How sustainability goals are influencing diagnostics

Diagnostics respondents ranked the relative importance of environmental considerations second from last and clinicians ranked them last in terms of characteristics of a new product. Given the importance of environmental social and governance (ESG) goals and the increasing focus on health equity in recent years, these views of companies and clinicians may reflect a lack of understanding and knowledge, or it may simply be that currently other challenges are more important. However, these views are short sighted, given that many healthcare systems have signed up to a net zero pledge and some have set stringent targets, placing expectations on suppliers within their supply chain to demonstrate how they are reducing their carbon footprints.

In response to specific questions about the extent to which ESG considerations are built into their product lifecycle, diagnostics companies were extremely positive (see Figure 12). However, companies are inhibited from being more ambitious in meeting ESG parameters by the financial costs of implementing change, a lack of corporate strategy and governance for ESG; a lack of ESG training across the organisation, and supply chain factors outside the organisation's control. All these issues need to be addressed in the next few years. Moreover, products developed today will likely come to market in 6-10 years, when more stringent regulations around climate are likely to be in place across Europe. This suggests that diagnostic companies should consider adopting a 'Sustainability by Design' mindset, alongside their 'Security by Design' mindset, in their approach to product development.

Figure 12. The extent to which ESG considerations are built into product lifecycles and the challenges inhibiting the company from being more ambitious in meeting ESG targets

Question: To what extent are ESG considerations built into your product lifecycle?



Question: Which of the following list of challenges do you think is the greatest factor inhibiting your organisation from being more ambitious in meeting ESG parameters?

Diagnostic company survey respondents
1. **The financial cost required to implement change – 21%**
2. **A lack of organisational strategy/governance on ESG parameters and targets – 14%**
3. **A lack of training/understanding of ESG considerations across the organisation – 12%**
4. Supply chain factors outside the organisation's control – 11%
5. A lack of consistency in reporting standards/metrics – 10%
6. The regulatory implications of process change – 9%
7. A lack of consistency in reporting standards/metrics – 9%
8. Lack of industry-wide collaboration – 8%
9. Lack of government/policymaker support – 7%

Source: Deloitte analysis of iResearch survey of 250 diagnostic companies.

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Turning overarching challenges into enablers

In addition to the above challenges there are six overarching challenges identified by our interviewees, which reflect the survey responses and which we used our literature review to explore further. These overarching challenges will need to be tackled as a priority if the future of diagnostics, which we discuss in the next section, is to be realised (see Figure 13).

A deep dive into these overarching challenges and an exploration of solutions to these challenges is presented in a separate companion report, *Reforming diagnostics: Turning challenges into enablers*. These challenges and solutions can be summarised as:

- **Digital infrastructure:** the wide variability in healthcare providers digital infrastructure (specifically interoperability and connectivity) was identified as the main obstacle in bringing a new diagnostic to market. Interviewees noted that interoperability, or the extent to which systems and devices can exchange and interpret shared data, relies on being able to establish connectivity and communication between medical devices and IT systems, and between data and workflows. For interoperability to work effectively, open platforms, based on open data standards are needed, with payers, providers, and technology vendors willingness to share data more effectively crucial to improving the effectiveness of diagnostic services.

> "You have to demonstrate efficiency and better outcomes. Then you must make it compelling for health authorities and make the business case for change."
>
> **Global medical technology company**

Figure 13. Diagnostics companies face six overarching challenges in the development and adoption of innovative products

Digital Infrastructure
- Data interoperability
- Connectivity
- Maturity of digital transformation
- Cyber security
- Data storage
- IT hardware
- Electronic health records

Product innovations
- Intellectual property
- Evidence generation
- Clinical studies (and access to samples)
- Competitor landscape
- Role of the gold standard
- Misdiagnosis impact

Supply chains
- Component shortages
- Supply chain resilience/agility
- Environmental, social and governance (ESG) commitments

Regulation
- Different markets/routes (CE, UKCA, FDA)
- Changes to regulation (MDR, IVDR, etc)
- Notified body capacity
- Cost and time
- Data regulations (e.g. GDPR)
- Cyber security
- Explainable AI
- Ethics

Funding/Investment
- Pre-market funding and investment
- Reimbursement pathways and timescales
- Device price and funding models
- Economic assessment
- Gathering evidence of device safety, improved outcomes and cost benefit
- Clinical pathway integration

Workforce and skills
- Healthcare culture and attitudes to technology enabled digital transformation
- Training and skills
- Staff shortages
- Leadership

Source: Deloitte analysis.

- **Regulation:** imaging machines, digital diagnostics and IVDs are subject to strict and evolving regulation. Companies across Europe are facing a growing number of challenges due to the implementation of the new Medical Device Regulation (MDR) EU 2017/745 in May 2021 and IVD Regulation (IVDR) EU 2017/746 in May 2022. These mean diagnostics companies have to comply with more onerous regulatory hurdles or risk products that fail to meet the new requirements being removed from the market. Immediate challenges include the need to comply with more stringent evidence requirements and lack of regulatory capacity to perform conformity assessments. These new regulations risk stifling innovation suggesting regulators should create target product profiles and clear indications of requirements to enhance transparency and guide product development conformity. Meanwhile diagnostics companies should consider implementing automated digital workflows to harmonise regulatory data submissions and improve data collection, governance, and reporting, and ultimately speed to market.

- **Product innovation:** Innovation pathways need to align to clinical needs and be co-developed with clinicians and other end users. In addition, companies must gather sufficient evidence to prove the safety and performance of their diagnostic to buyers and end-users. Furthermore, new value-based reimbursement pathways place an emphasis on obtaining real world data and evidence (RWD and RWE) to provide a greater level of insights. As diagnostics become more connected and generate increasing quantities of personal medical data, maintaining the security of data crucially important, consequently 'security by design' needs to be embedded from the outset.

- **Funding and investment:** while access to funding and investment was a challenge pre-pandemic, the new MDR and IVD regulations appear to be undermining access to innovation funding while increasing the funding needed to meet the costs of the more exacting evidence requirements. While diagnostics and the detection of disease is currently a 'hot area' for investment, providing evidence of improved patient outcomes and likelihood of adoption is required to instil confidence in investors. Strategic partnerships, including merger and acquisition (M&A) deals, license agreements and co-development can reduce investment risk. In Europe, a more risk-averse approach to investing is generally taken compared to the US, making it harder for companies to raise funds on innovative products. Moreover, each European country has its own reimbursement policies meaning a European wide innovation ecosystem is needed to support manufacturers in the development and launch of products.

- **Supply chain:** Supply chain issues affecting European manufacturers have arisen as a result of Brexit, the post-pandemic recovery and geopolitical turbulence. Our interviewees have developed multiple strategies to safeguard their supply chains, including higher levels of inventory and access to multiple sources for materials and components. There is also a need to build flexibility into the design of diagnostics wherever possible, including considering where components may change, as gaining approval for a suite of alternative components can mitigate later product supply issues. Increased regulatory requirements for product traceability and global ambitions for achieving net zero, are expected to have major supply chain implications. Enhancing end-to-end supply chain visibility through digitalisation, boosting supply chain agility (through stress testing business continuity plans and building redundancy into operations) and utilising broker relationships can help build supply chain resilience.

- **Workforce:** Across Europe healthcare systems are facing significant workforce shortages. Adoption of new diagnostic technologies can help improve efficiency and release clinicians' time to care, including shortages in the radiology and pathlogy workforce. Our surveyed clinicians felt a lack of workforce training and skills in new technologies was a core barrier to technology adoption. While healthcare systems should provide such training, diagnostic companies could help by ensuring they provide appropriate learning materials, on-demand support, and on-site training. Clinicians suggest that the most valuable sources to learn about medical device technologies are online videos and on-demand courses. A priority for diagnostics companies should be to develop accessible training materials that are easily accessible to device end-users.

"The problem is not technology or cost – the problem is having the people in the healthcare system trained."

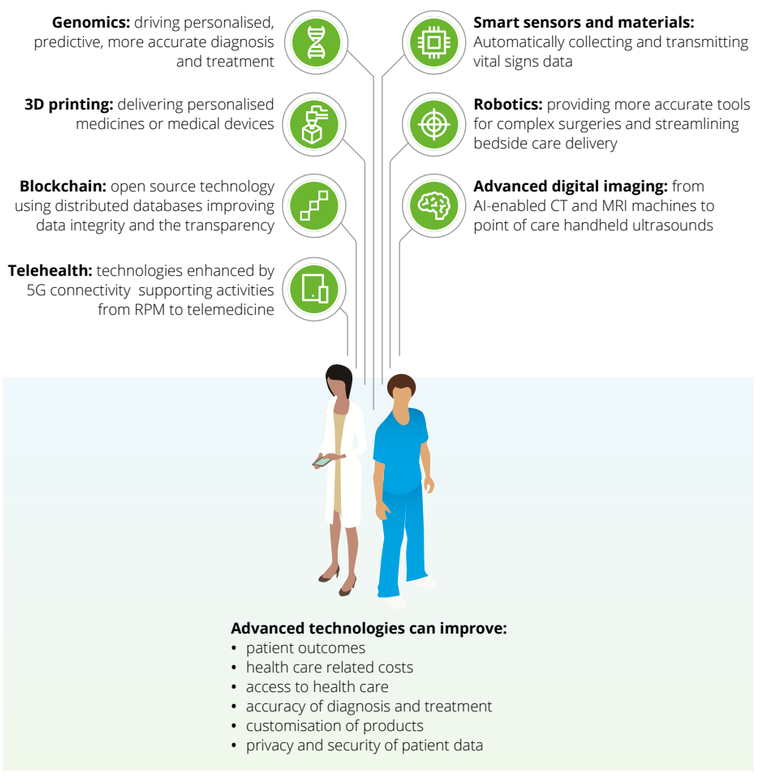
Wearables and AI company

A new diagnostic paradigm enabling 4P medicine

Disruptive technologies, science, and advanced informatics are coming together to transform the way we prevent, diagnose and treat disease. The diagnostics industry is now joining the fourth industrial revolution. A new diagnostic paradigm is emerging in which digitalisation, robotisation and automation are giving rise to smart laboratories and smart imaging systems that can readily handle the increasing demands from healthcare providers and consumers, at speed and at a lower cost. Our research has identified technologies that are already enhancing diagnosis, and those that are likely to transform diagnosis in the future, alongside a renewed momentum for partnerships between traditional and non-traditional players.

Our 2020 report *The future unmasked: Predicting the future of healthcare and life sciences in 2025* predicted that by 2025 clinicians would be empowered by a new diagnostic paradigm,with diagnoses and treatment decisions based on 4P medicine, and driven by technological and scientific advancements. Specifically, the report predicted that technological breakthroughs in AI, nanotechnology, quantum computing and 5G would enable faster, customised diagnostic pathways, and that clinicians would be supported by AI-enabled clinical decision tools to help deliver hyper-personalised evidence-based prevention and treatment interventions.[44] While the technologies to realise this future are available today (see Figure 14) most have yet to be adopted at scale. We therefore used our surveys of clinicians and diagnostics companies to get a more detailed understanding of how the future of diagnostics might evolve over the next five to ten years.

Figure 14. The technologies that are available to drive the future but which are yet to be adopted at scale



Source: Deloitte LLP, 2018.

"To get innovation back on track and to get innovation into Europe, all stakeholders need to rethink the way they work together."

Notified Body

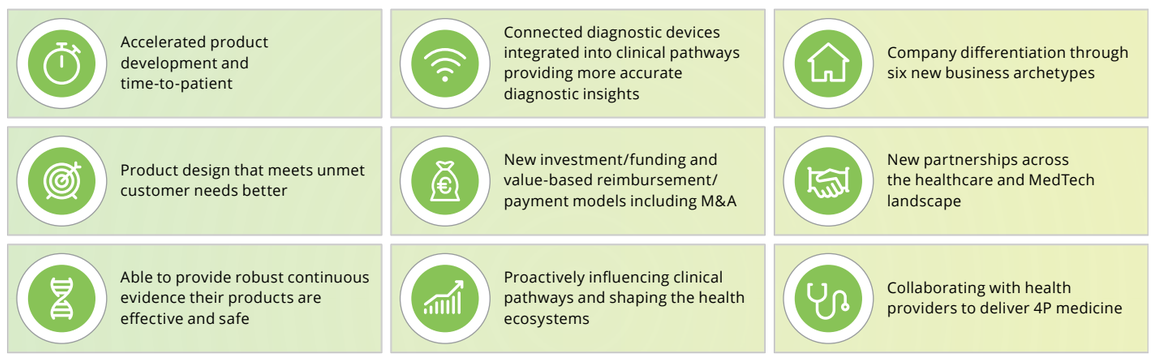
How disruptive technologies will transform diagnostics over the next five to ten years

The capability and accuracy of smart diagnostics are increasing at a rapid rate, and as a result the diagnostics landscape is undergoing an accelerated transformation, leading to a new diagnostic paradigm to benefit the healthcare system and patients (see Figure 15). It is also creating opportunities for the diagnostics industry (see Figure 16).

Figure 15. The benefits for healthcare systems of a new diagnostic paradigm

Source: Deloitte analysis.

Figure 16. The opportunities for the diagnostic industry of a new diagnostic paradigm



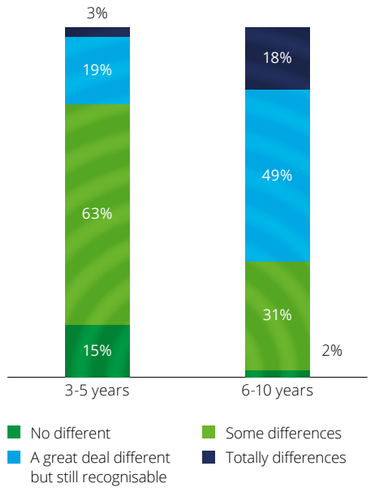
Source: Deloitte analysis.

Among the clinician respondents to our survey, 63 per cent suggested that as the healthcare sector transitions from a focus on acute intervention to one centred around prevention and wellness, the future of diagnostics will look somewhat different in 3-5 years' time, and two-thirds think it will look 'a great deal' or 'totally' different in 6-10 years' time (see Figure 17).

The most important changes needed to improve the future of diagnostics

To realise the future of diagnostics it will be necessary to educate and train clinicians, to enhance their understanding of research, data science and genomics, digital technologies and AI. Other crucial enablers for the future will be collaboration between stakeholders and access to real-time data (see Figure 18).

Figure 17. The likely evolution of how diagnostics will look in 3-5 years and 6-10 years



Source: Deloitte analysis of Sermo survey of 751 clinicians. Question: As the health sector transitions from a focus on acute intervention to one centred around prevention and wellness diagnostic technologies will likely evolve; how different do you envision the future of diagnostics

Figure 18. The most important changes needed to improve the future of diagnostics

Clinician survey respondents

1. **Education and training of clinicians to enhance understanding of research, data science and diagnosis derived from genomic, digital and AI devices – 40% (15%)**
2. **Collaborations between healthcare and MedTech organisations to design diagnostic devices to address areas of unmet need – 31% (10%)**
3. **Access to real time device user/patient data – 31% (10%)**
4. Predicting disease from large scale datasets (including whole genome sequencing) – 30% (12%)
5. Embedding novel sensors and diagnostic technologies into clinical pathways – 28% (9%)
6. Enhancing existing technologies with decision support – 25% (6%)
7. The health system introduces new incentives to improve equitable access to diagnostic device(s) – 25% (8%)
8. Data sharing: patients are willing to share their data with you on understanding that you comply with a clear policy on the use of that data – 24% (8%)
9. Predicting treatment responses – 23% (8%)
10. Healthcare organisations collaborate with MedTech companies in designing new payment models that reward providers for health outcomes and better management of health and wellness – 23% (7%)
11. Enhancing the digital infrastructure to improve the storage and security of data – 20% (8%)

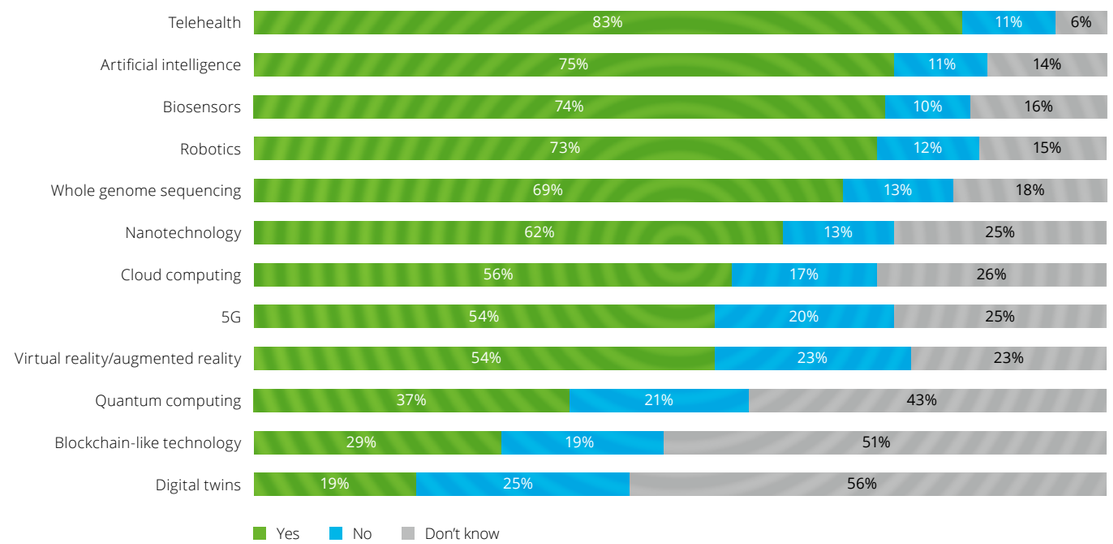
Source: Deloitte analysis of Sermo survey of 751 clinicians. Q. What are the three most important changes that would improve the future of diagnostics? Note: Multiple choice questions; percentage represents proportion of total respondents selecting a particular option as one of the top three changes. The figure in brackets is the percentage choosing as the top challenge.

The technologies expected to transform the future of diagnostic pathways

In our 2018 report *MedTech and the Internet of Medical Things (IOMT): How connected medical devices are transforming healthcare*, we highlighted that major advance in wireless technology, miniaturisation and computing power had started to drive MedTech innovation, with the development of many connected medical devices that generate collect, analyse and transmit data. This is leading to the emergence of the Internet of Medical Things (IoMT), a network of connected medical devices, software applications, health systems and services that can help healthcare organisations streamline their clinical operations and workflow management, and improve patient care, even from remote locations.[45] The IoMT has the potential to transform the diagnostics industry's role and relationships within healthcare.

Our clinician respondents expect over the next three to five years to adopt more widely many of the advanced technologies that are available today, to improve the efficiency and effectiveness of diagnosis (see Figure 19). The most likely are telehealth (83 per cent of respondents), AI (75 per cent), biosensors (74 percent) and robotics (73 per cent). Our research suggests that telehealth services will become a core part of routine clinical practice, guiding at home testing and discussions about results, and triaging care needs and clinical follow-ups. Improvements in the healthcare infrastructure and an increasing number of diagnostic telehealth platforms are contributing to this advance, although progress is restrained by access challenges and the high costs associated with remote monitoring devices. Partnerships and acquisitions by major market players provide further opportunities for growth.[46]

Figure 19. Technologies that clinicians believe should improve the efficiency and effectiveness of diagnostics in the next 3-5 years

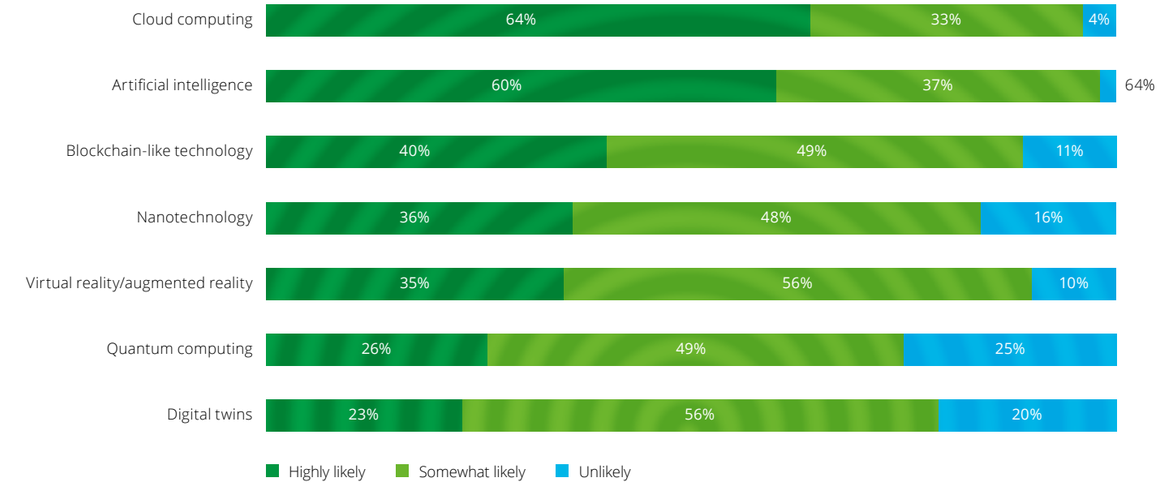


Source: Deloitte analysis of Sermo survey of 751 clinicians. Q. Which of following technologies do you expect to improve the efficiency and effectiveness of diagnostics in the next 3-5 years outcomes?

However, for some of the more novel technologies like digital twins, blockchain and quantum computing (which Deloitte as well as most of our interviewees believe will make a real difference) over two-thirds of clinicians said 'no' or that they didn't know. However, to better understand and make use of the data from their devices, almost 100 per cent of our industry respondents expect to introduce cloud computing and AI over the next five years, and there is also a growing likelihood that they will begin to adopt the other technologies (see Figure 20).

Our research identified a large number of diagnostic devices that are beginning to disrupt diagnostics, such as at home blood tests (see Case study 3) and urinalysis products that detect UTIs and do home kidney and prenatal testing with smartphone-powered clinical urine testing (we featured Healthy.io as a case study in our European digital transformation report).[47] These and other technologies such as genomics can also enable the provision of 4P medicine (see Case study 4).

Figure 20. The technologies diagnostic companies expect to introduce over the next five years



Source: Deloitte analysis of iResearch survey of 250 MedTech companies. Q What technologies does your organisation plan to introduce over the next five years to better understand, protect, and use the data generated from your medical devices?

Case study 3. Bloom Diagnostics AI -enabled lateral flow test technology (Switzerland)

Bloom Diagnostics is a Swiss MedTech company developing hardware and software for quick and easy diagnostic testing. The company develops smart blood tests that utilise a custom lateral flow assay technology stack paired with data analysis and AI to deliver rapid, accurate testing of ferritin, thyroid function, inflammation and kidney function. Its algorithms learn from each test performed, allowing for new features and updates to be implemented seamlessly.

The Bloom System is centred around the Bloom Lab, a desktop device that can quantify analyte concentrations in the blood using a Bloom Test strip. The user inserts the test strip to measure their ferritin levels, thyroid function, bodily inflammation or kidney function. After pricking a finger, a drop of blood is placed on the Bloom Test strip. While the measurement is being conducted, users answer questions about their health and lifestyle in the Bloom App. This information is combined with the quantitative test result to provide personalised feedback, the Bloom Report, which is displayed in the app. Every part of the system is connected to the cloud.

The Bloom Lab is currently priced at €299 ($297). It needs only to be purchased once and can be reused for all tests the company offers. Bloom expects to launch new tests for other biomarkers, as well as new hardware features for the Bloom Lab and general improvements to the Bloom System via AI. Bloom is also looking to expand its geographical reach, for example to the US in 2023.[48]

"Oncology is the biggest mover in precision medicine, but we are seeing the emergence of precision medicine in other areas. Genomics and companion diagnostics can be used to get a broad image of the patient, resulting in better treatment decisions and faster times to those decisions."

Sequencing technology company

Case study 4. How Illumina's sequencing technology is transforming diagnosis

Illumina's next generation sequencing technology (NGS), including the 'NextSeq' system range offers cheaper and faster sequencing solutions compared to traditional sequencing methods.[49] Whereas 20 years ago sequencing a whole human genome cost around $100 million, Illumina has supported the dramatic reduction in cost to $600 and also major improvements in speed, and continuing innovation is increasing the accessibility of this technology.[50]

NGS technologies can also increase the efficiency and scalability of sequencing, aiming to improve availability and access, by enabling whole genomes to be sequenced more rapidly (with each DNA letter read 30 times). Further, the Illumina DRAGEN Bio-IT platform offers accurate, comprehensive, and efficient secondary analysis of NGS data in under half an hour.[51] [52] Furthermore, the technology provides higher sample throughput and greater sensitivity, making whole genome sequencing more accessible and practical, and enabling greater understanding of disease and treatment viability, and improving patient outcomes.[53]

Applications include sequencing cancer samples to study rare variants, identifying novel pathogens and studying the human microbiome for example.[54] Illumina's technology has supported clinicians and academic researchers to make a significant impact in their field, including:

Comprehensive genetic profiling (CGP). In March 2022, Illumina announced the first launch of TruSight™ Oncology (TSO) Comprehensive in Europe, a single test that assesses multiple tumour genes and biomarkers to reveal the specific molecular profile of a patient's cancer and inform precision medicine decisions.[55] Furthermore, CGP has been implemented in Hungary to help physicians better identify cancer types and deliver targeted therapies, and increase understanding of which tumour types benefit most from this approach. [56]

The COVID-19 pandemic surveillance.[57] Illumina's NGS technology has been adopted in over 10,000 labs and 115 countries to monitor transmission and help develop therapies and vaccines during the pandemic. This includes sequencing the first SARS-CoV-2 genome in Wuhan, enabling the UK to map the spread of the virus, and providing an open source toolkit to enable researchers to detect the virus and contribute data to public databases, supporting global research.

Figure 21 provides examples of the disruptive technologies that *Digital.Health* features as AI-incorporated diagnostic tools that can enable and 'upskill' clinicians (and patients).

From vital signs monitoring to mobile-lab-on- a-chip these can help reduce costs and improve accessibility, helping to democratise diagnostics and care.

Figure 21. IOMT and AI incorporated diagnostic tools enabling and upskilling clinicians

Transforming point-of-care ultrasound – Butterfly iQ is the world's first FDA Cleared, CE Marked single-probe, whole body ultrasound system. A hand-held device that turns a doctor's smartphone into an ultrasound machine, for instant scanning in life-saving situations. Used in diagnostic Imaging, Cardiology, Critical Care, Emergency Medicine, Gynaecology, Nursing, Radiology, Anaesthesiology, Primary Care.

Butterfly iQ | Digital Health

Transforming detection of abnormal heart rhythms – KardiaMobile 6L – The first FDA-cleared six-lead personal EKG. Detects Atrial Fibrillation (Afib) or Normal heart rhythm anytime, anywhere. 6-lead EKG data gives your doctor a more complete view of the heart, and ability to identify other cardiac arrhythmias. AliveCor has over 100 per reviewed articles.

KardiaMobile 6L | Digital Health

Identifies early signs of clinical deterioration in chronically-ill patients – Spry's Loop System is the first FDA-cleared end-to-end chronic care remote monitoring system for early interventions. The Loop system helps provider organisations improve outcomes in patients with chronic conditions by identifying early signs of physiological deterioration up to a week prior to an exacerbation. The Loop is based on an extensive set of machine learning and expert systems algorithms that contextualise real-time, continuous physiologic data and pinpoint signs of deterioration Measures -Heart rate, oxygen saturation (SpO2), Breathing rate.

Spry Health | Digital Health

Anytime anywhere data supporting clinical decision making – KardiaPro is a FDA Cleared, CE marked. web-based, portal that presents medical-grade patient data from the most clinically-validated and widely-used ECG and blood pressure monitoring devices. KardiaPro is used by providers to support clinical decision making. Actionable data is organised for efficient triaging. KardiaPro can monitor patients anytime, anywhere. Used for Health Management, Laboratory & Diagnostics, Triage.

KardiaPro | Digital Health

Wrist and chest monitor for measuring 13 vital signs continuously, wirelessly, and in real-time – Biobeat is a unique AI-enabled RPM device whose FDA-cleared, health-AI platform includes a disposable short-term chest-monitor and a long-term wrist-monitor, both using a photoplethysmography-based (PPG) sensor to provide continuous accurate patient readings of 13 health parameters, wirelessly, and in real-time (including real-time, cuffless blood pressure, pulse rate, respiratory rate, blood oxygen saturation, temperature, stroke volume, cardiac output, one lead ECG (only chest-monitor). Using a wrist or chest monitor it collects millions of data points per patient per day. The platform also enables customisable alerts for each measurement and personalise thresholds.

Biobeat | Digital Health

Comprehensive imaging – Brainomix E-Stoke Suite – is a comprehensive imaging solution, empowering clinicians across all stages of the stroke patient pathway and supporting the thrombectomy decision-making process, from non-contrast CT interpretation to collateral assessment and LVO detection, to more advance perfusion –based assessments. It specialises in the creation of AI-powered imaging biomarkers that enable precision medicine for better treatment decisions.

Brainomix | Digital Health

Source: Digital.Health, A site dedicated to the field of digital health, digital medicine and digital therapeutics. Created and curated by Dr Daniel Kraft **Diagnostics & Monitoring | Digital Health, https://digital.health/digital-diagnostics**

New diagnostic pathways will be crucial drivers of the future of health

Prediction, prevention and early diagnosis will be central to the future of health, a future that will be driven by transformational and disruptive diagnostic technologies While diagnostics companies are well-positioned to drive the future of health, they cannot do it alone and will require partnerships with consumer technology and specialised digital health companies.

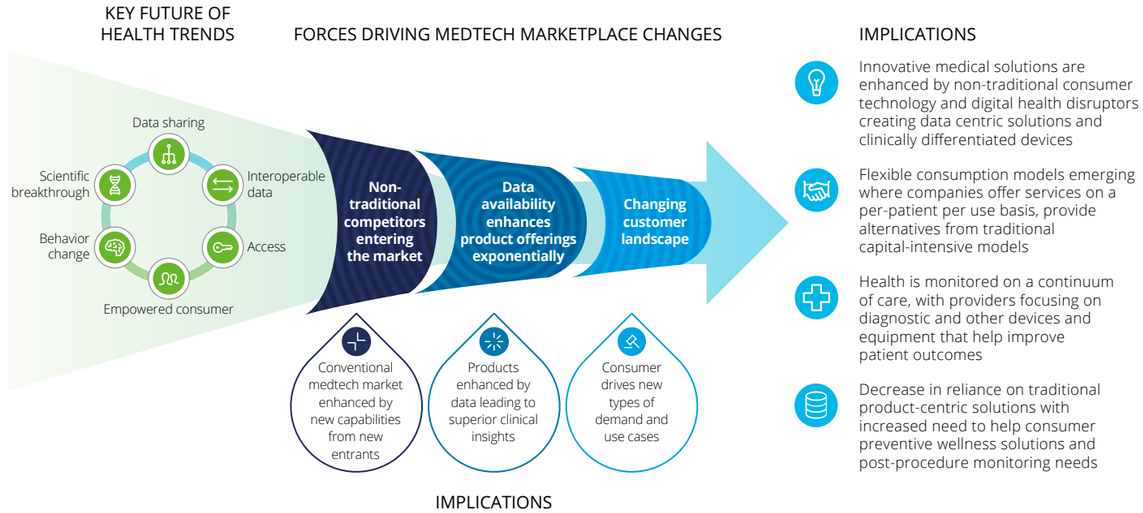
Several new trends are emerging which will shape this inter-reationship still further, from biosensors and companion diagnostics to liquid biopsies and new direct to consumer tests. Moreover, the future of radiology and pathology will be revolutionised by AI. We have used our vision of a new diagnostic paradigm to create three clinical pathways that demonstrate how healthcare can use innovative diagnostics to deliver 4P healthcare, and which illustrate what the future of diagnostics, and the future of health might look like.

The future of health and the development of new tyes of diagnostics companies

Deloitte expects prevention and early diagnosis to be central to the future of health and that sophisticated tests and tools could mean most diagnoses (and care) take place at or close to people's homes. Deloitte also believes that the future of health will be driven by a ubiquitous, proactive, and integrated system of health and wellbeing where transformational technologies (such as AI, quantum computing, cloud storage, augmented and virtual reality) are poised to play a pivotal role. [58]

We expect medical devices to combine hardware and software to help improve and democratise access to diagnostics. As the focus of healthcare shifts towards prevention instead of treatment, future devices will alert care teams through real-time sensors about potential health issues before they become symptomatic. Although diagnostic companies and other parts of the MedTech industry are well-positioned to drive the future of health, most cannot do it alone and instead will need to partner with consumer technology and specialised digital health companies to meet the challenges of the changing market (see Figure 22).[59]

Figure 22. The Future of Health trends driving changes in the MedTech marketplace with consumer needs and data driving new solutions that go beyond the device



Source: Deloitte LLP.

"We need to be diagnosing faster. This might mean more or new tests, or new forms of continuous diagnostics like step count and cadence so that we can diagnose way before you feel ill. The sooner we start to monitor for illness and get patients into the right pathway the sooner we can make a difference."

Industry body

Future of health trends that will enable the new diagnostic paradigm

Interoperable data and open secure platforms: will enable the future of health. For example, open and secure data platforms would allow individuals to perform a diagnostic test at home, verify the diagnosis, order the necessary prescription, and have it delivered to the home, perhaps via drone. Or infections may be identified and addressed before any symptoms appear. In both these scenarios, consumers will address health issues at home, allowing physicians to focus on cases that require human intervention. Companies are already beginning to incorporate real-time biosensors and software into devices that can gather and share individual, organisational, population and environmental data, and develop platforms that aggregate, store and derive insights from the data.[60]

New payment and reimbursement models: will be adopted by future diagnostic companies using innovative contracting and value-based care (VBC) arrangements such as risk sharing, with payment pathways encouraging adoption of VBC payments at scale. We also expect payer funding to be extended to remunerating RPM and digital therapeutics, and for IVDs there will be a new reimbursement evaluation framework aimed at improving health outcomes in a sustainable way. These changes are not yet occurring at scale, but we expect payment and business models for diagnostic services to change even further in the future, for example with companies contracting directly with hospitals, health systems, and physicians and sharing in the savings achieved through value-based contracts.

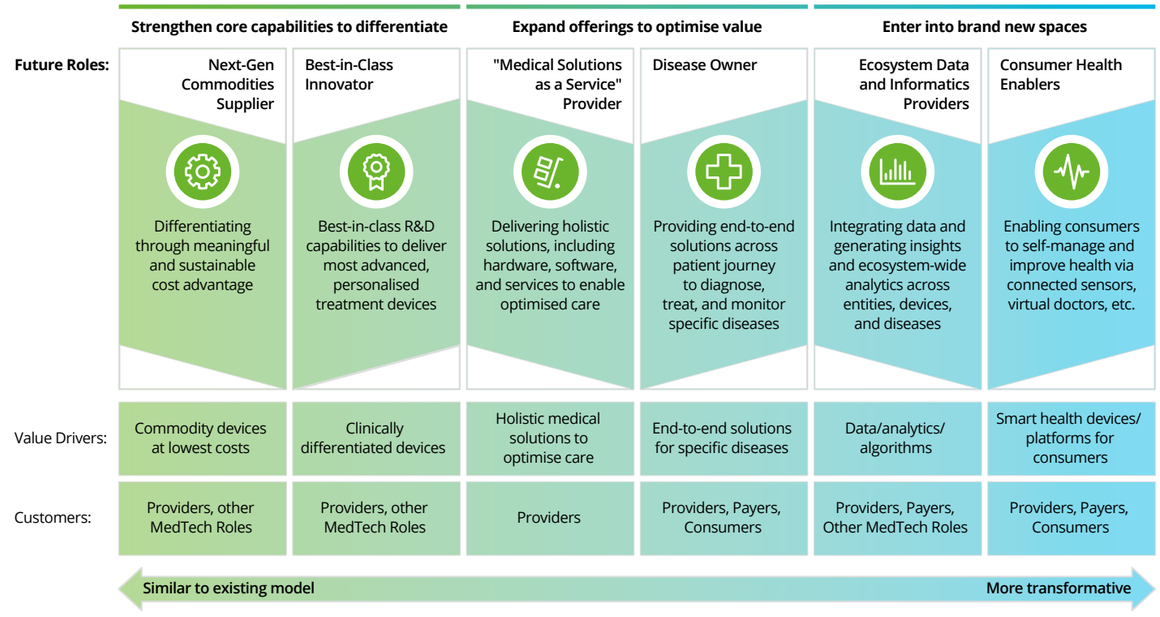
Collaboration will be essential: in designing new payment models that reward all partners for improved health outcomes and better management of health and wellness. VBC models will help re-allocate resources to where they can be most effective. Investors are likely to look closely at hybrid models where technology companies combine virtual care with a retail experience to enable consumers to access primary care, behavioural health, or specialty care through a combination of virtual health and in-person visits at a retail location.

Some new payment arrangements are already in place including:

- Bruin Biometrics, which has developed a hand-held wireless scanner that detects pressure ulcers (and helps caregivers or providers prevent the formation of pressure ulcers). The company has signed risk sharing agreements with providers in the UK which involve payment tied to early detection of ulcers.
- In the US, Philips and Jackson Health System have entered an 11-year enterprise-monitoring-as-a-service (EMaaS) partnership. Under the agreement, Jackson Health can adopt patient monitoring systems, such as wearable biosensors, for a per-patient fee and adopt standardised patient monitoring for each care setting across its network. Philips owns the hardware, software and networking solutions related to patient monitoring technologies. Jackson pays for monitoring usage hours only.[61]

These trends and developments mean diagnostics companies will need to consider what role they would like to play in the future healthcare ecosystem, with six new roles for diagnostics companies emerging. Companies have a choice as to whether to remain 'a commodity supplier or best in class supplier, a solutions-as-a-service provider or a disease owner, a data and informatics provider or consumer health enabler', or a combination of all of these options (see Figure 23).[62]

Figure 23. As the diagnostic industry evolves, we anticipate six roles to emerge for companies to consider



Source: Deloitte LLP.

Some trends that will shape the future of diagnostics

Biosensors and the growth in companion diagnostics

Companion diagnostics (CDx) are tests (often in-vitro) that support 'the safe and effective use of a specific medicinal product, by identifying patients that are suitable or unsuitable for treatment'. They also monitor treatment response and can accelerate access to new and effective treatments.[63] [64] While oncology has been the biggest driver of precision medicine to date, CDx in future will support precision medicine for a wide range of therapy areas, including cardiovascular, reproductive, and neurodegenerative diseases. Furthermore, by combining next generation sequencing (NGS) that enables investigation of multiple biomarkers with diverse patient and disease data, a holistic genetic level patient view can beobtained, providing insights that lead to better and faster treatment decisions for multiple conditions.[65]

Analytical platforms are diverse, and the FDA classifies CDx assays as high-risk devices, with the regulatory path for these almost exclusively requiring submission of a Premarket Application (PMA). By the end of 2020, the total number of CDx assays approved by the FDA had reached 44, mostly in oncology and haematology, but the field has developed rapidly and by August 2022 there were 143 listed.[66] [67] In Europe CDx are subject to the new IVD Regulations based on a classification system that requires a CDx to undergo a conformity assessment by a notified body.[68] The EUDAMED database currently lists 48 companion diagnostic products on the EU market (under old and new regulations).[69]

Biosensors have the potential to revolutionise healthcare management and diagnosis protocols in several ways, from simple monitoring systems to predictive and early diagnosis. As the costs of next generation sequencing (NGS) continue to fall, new biosensor technologies for multi-parameter detection of diagnostic markers, such as protein expression, will emerge; and companion diagnostics will become an increasingly valuable and accessible tool that supports 4P medicine and advanced drug development. Although gene-based companion diagnostics are becoming increasingly common there is a complex relationship between genotype and phenotype; and relying on genomic data alone risks missing vital information. Protein biomarkers can give a more sensitive and accurate representation of a patient's phenotype, providing more accurate diagnosis.[70] If 2002-2020 was the age of genomics and a crucial enabler of the evolution of diagnostics, 2020-2030 will be the decade of proteomics and a more revolutionary future for diagnostics.

Until recently, the limitations of proteomics technologies restricted the development and commercialisation of protein-based companion diagnostics. However, advances in mass spectrometry have helped make unbiased, reproducible high-throughput proteomics a reality, supporting the discovery, development and commercialisation of companion diagnostics for a wide range of diseases. For example Biognosys, a company that offers large-scale proteomics solutions, combines depth of proteome analysis with reproducible and precise quantification to identify and validate the most promising protein biomarkers for end-to-end companion diagnostics, from bench to bedside.[71]

Liquid biopsies and minimum residual disease (MRD) monitoring,

Early detection of cancer is a crucial requirement in all healthcare systems. It has the potential to have a significant impact, since many cancer deaths occur in cancers without recommended screening tests.[72] Sufficient sensitivity for early-stage cancers and broad reimbursement are two key requirements for realising the full potential of these tests. MRD monitoring is an important breakthrough which uses ultrasensitive liquid biopsy tests to enable more effective surveillance and earlier detection of recurrence than existing tests or imaging. In addition to this early sensitive detection of cancer and cancer recurrence via tumour DNA in the blood, liquid biopsies can be used to assess drug response and detect other biomarkers of disease, for example:

- In 2021 GRAIL launched Galleri, the first multicancer early detection (MCED) test commercially available in the United States as a laboratory-developed test. The test sequences cell-free DNA in the blood to detect more than 50 cancer types and is available on prescription in the US. It detects many cancers not commonly screened for today, to enable earlier treatment, and it can identify where in the body the cancer is coming from with high accuracy.[73] [74]

- In 2020, C_2N Diagnostics, LLC, launched a blood test to determine likelihood for the presence of amyloid plaques in the brain, a pathological hallmark of Alzheimer's disease. The test, performed in C_2N's CAP-accredited, CLIA-certified Laboratory, uses highly sensitive liquid chromatography-mass spectrometry technologies. While the blood test by itself cannot diagnose Alzheimer's disease in the clinic (a clinical diagnosis is made by a health care provider), the test is seen as an important new non-invasive tool for clinicians to aid in the evaluation process. Minimizing both false negatives and false positives will be important for driving widespread adoption. [75]

The future of diagnostics | Technology driven personalised and preventative healthcare in Europe

DTC-led diagnostics

Consumers are increasingly interested in using diagnostic tests to understand their health better. They want diagnostic tests that are accurate, convenient, fast and affordable. The pandemic has made DTC tests a more common part of everyday life and popularised at home testing as an alternative to less convenient (but currently more accurate) centralised testing. At home diagnostics may benefit the healthcare system, by reducing the number of in-person visits for routine tests and reducing the cost of care.

Most DTC models (not including COVID-19 self-tests) send samples to approved certified labs and then receive results, which are sometimes reviewed by physicians. There has been significant investment in the past two years, increasing the number and variety of DTCs. However, it is difficult for consumers to assess or compare the reliability of different tests. Many are not covered by the healthcare payers, which is a barrier to widespread adoption.

As the market grows for more-complex at home tests like cancer screening and organ function tests, patients will need support for interpreting the results and determining the next steps to take. Patients need to be aware of the possibility of a false positive for these screening and diagnostic tests. As the market matures, consumers, insurers, regulators, clinicians and test providers will all need to confront the ethical issues that arise around access, cost and increased quantities of available diagnostic information.

The future of the pathology laboratory

Although the COVID-19 pandemic increased understanding of the importance IVD testing, it also highlighted serious staffing constraints in pathology services. There is a global shortage of pathologists, and numbers are predicted to fall by 30 per cent by 2030.[76] A detailed global analysis identified big disparities, with two-thirds of the pathologist workforce located in just 10 countries, including the US, Canada and Europe (Europe was considered to have moderate shortages). There are also wide disparities within countries themselves. [77] Innovative technology such as robotic process automation (RPA) is seen as a logical solution along with digitalisation to help overcome the staffing shortages, as well as improve the precision and speed of results.

Pathology services were highlighted by our interviewees as an area ripe for automation, with digital transformation and advanced analytics such as machine learning and decision support having the potential to increase efficiency and enhance capacity significantly. For example, the accelerated adoption of automated on-demand molecular testing, driven by the pandemic, has led to the introduction of advanced equipment that carries out repetitive manual sample processing steps enhancing test turn-around-times, throughput, and quality (see Case study 5).[78]

Case study 5. Improving patient outcomes with AI-powered pathology

PathAI is a global leader in AI-powered technology for pathology, whose mission is to improve patient outcomes with AI-powered pathology. In August 2022, it announced two significant regulatory milestones:

- 510(k) clearance from the US FDA for AISight Dx, a lightweight, web-based digital pathology slide viewing platform for the purpose of primary diagnosis in clinical settings
- AISight Dx also received a CE mark for IVD use in the EU, designating conformity with European health, safety, and environmental protection standards.

These designations pave the way for IVD use of AISight Dx with the Philips Ultra-Fast Scanner in the US and the EU.[79] The company is also partnering with biopharma and clinical stakeholders to leverage the power of proprietary AI and digital pathology tools to improve precision medicine. The company's technology fuels initiatives from drug research through IVD diagnostic development and distribution to labs to deliver faster, more accurate diagnoses, match patients with the most effective treatments and aid in the development and approval of more life saving therapies.[80]

"Clinical decision support tools will be used to simplify and optimise the use of our time, but also offer better clinical care to increasingly complex pathways."

Academic and Clinical Consultant

More generally, digitalisation, robotisation and automation are giving rise to the establishment of highly flexible 'smart laboratories' that can handle both routine/high volume analyses and highly customised analyses at competitive outcomes and prices. This is coupled with an ongoing integration of the entire value chain, from subcontractor to customer. This wave of integration is expanding to encompass different fields of science such as biotechnology, genetics, and nanotechnology; and is generating new disruptive technologies. Computational pathology, unlocked through information integration and advanced digital communication networks, has the potential to improve clinical workflow efficiency, diagnostic quality, and ultimately create personalised diagnosis and treatment plans for patients.[81]

In future, IVD companies and clinical laboratories will need equipment with a high degree of flexibility and automation, to be able to adjust their workflow continually for new applications. This will necessitate built-in flexibility in clinical diagnostics applications, to switch for example between customised and generic services or to switch to new market segments (such as immunoassay, mass spectrometry, or molecular testing). To survive in this rapidly changing environment, clinical laboratories will need to adapt quickly to constant shifts and unpredictable requirements.

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The future of radiology

Radiologists are facing increased workloads and pressures. A 2019 Philips study found radiology job stress levels to be 'moderate' or 'extreme' for up to 97 per cent of staff, depending on location. The pandemic has added to the pressures.[82] There is also a global shortage of radiologists with over two-thirds of the global population having limited or no access to radiologists. Access to trained radiologists is limited for millions of people who live in remote areas and even in the more developed European countries there are disparities in numbers of radiologists per 100,000 population. AI can help bridge the gap between remote communities and state of the art medical centres. Automated screening with AI can help radiologists to triage patients remotely by flagging abnormal medical images. AI embedded in mobile devices can help screen people who live in rural areas without hospitals. Such devices are designed to work in places without electricity and without internet access.[83]

Cloud-based image exchange built into electronic health records (EHRs) have led to the demise of CDs as a medium for exchanging images. The benefits from this have included streamlining workflow, avoiding the need for multiple logins across diverse applications as providers search for the correct patient, and reducing the loading of unnecessary images into the local Picture Archiving Communication Systems (PACs). The use of AI has further enhanced radiology, with several companies delivering improved outcomes using advanced analytics (see Figure 24).

Figure 24. Some of the imaging companies that are improving outcomes

Product/company	Technology	Impact
Jiva (Jiva.ai Ltd)	AI platform that makes it easy for both technical and non-technical users to create multimodal AI (combining multiple data types/behaviours) via a no-code interface.	Jiva aims to be the go-to platform for any healthcare and life sciences business that wants to create an AI solutions fast – whether it's imaging, text or time-series analytics. Jiva's capability in AI creation means that R&D can be compressed from months to weeks or even days of development. Previous applications of this technology have included an MRI-driven prostate cancer diagnostic (with a sensitivity of 91 per cent and a specificity of 88 per cent), bone fracture diagnostics and liver disease screening.[84]
BoneView (Fujifilm/GLEAMER)	An AI software integrated into Fujifilms imaging systems and used to detect and highlight regions of interest in X-rays to help identify bona trauma at the point of care.[85]	In a clinical study this technology improved the sensitivity and specificity of fracture detection and reduced false positives by over 41 per cent. The solution also improved efficiency, reducing radiograph reading times by 6.3 seconds.[86]

Since 2020 there have been a growing number of regulatory approved innovations. The benefits of these solutions vary from reducing image acquisition and reconstruction times, reducing image noise, automating stroke assessments, and predicting Alzheimer's progression. For example:

- In May 2022 the FDA cleared the world's first AI-driven portable and automated 3D breast ultrasound scanner. In just two minutes, the system automatically scans the entire breast volume and offers 3D visualisation of the breast tissue. The ATUSA developed by iSono Health system does not require a radiologist or ultrasound technologist for image acquisition; however interpretation the images requires a physician with training in breast ultrasound.[87]

- Niramai has developed a low-cost portable device to detect early-stage breast cancer using machine learning. This portable device can be used in places without electricity and without internet access, and its uses include screening women for breast cancer in the privacy of their own homes.[88]

- Aidoc's AI based decision support software analyses medical imaging data, flags findings, and alerts radiologists, surgeons, and neurologists about suspected positive cases. Aidoc has nine FDA-cleared and CE-marked solutions for detecting many acute anomalies such as brain aneurisms, C-spine and rib fractures, pulmonary embolisms, pneumothoraxes, and intracranial haemorrhages.[89]

- Oxipit was granted CE Class IIb certification in Europe for ChestLink autonomous AI imaging suite. ChestLink AI reviewed more than 500,000 X-rays across multiple locations with over 99% sensitivity and zero clinically relevant errors.[90]

- Scientists at the University of Copenhagen helped radiologists reduce their workload by three-fifths, using AI to help screen for breast cancer.[91]

One underlying common thread in the AI-enabled transformation of both pathology and radiology is the importance of collaborations (see Case study 6).

Partnerships with consumer technology disruptors will shape the future of diagnostics and the future of health

To remain relevant, diagnostics companies will need to develop an in-depth understanding of clinician and patient needs to help develop future care models. Partnerships with consumer technology companies who can draw on their experience of brand, engineering expertise and knowledge of customers, can help shape this future and transform clinical pathways.[92] Indeed large consumer technology companies ('tech giants') are increasing their involvement in healthcare, including diagnostics.[93] Examples include:

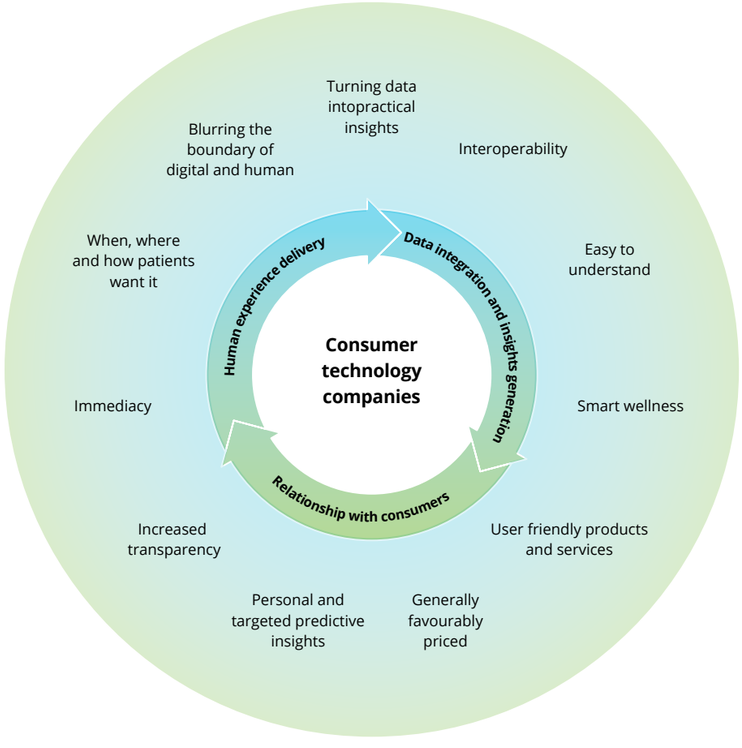
- the CE-marked irregular heart rhythm notification feature on the Apple Watch.[94]

- Amazon's July 2022 announcement of its intent to acquire US subscription-based healthcare provider One Medical (adding to its existing online pharmacy and telehealth moves).[95]

- Alphabet's Verily Life Sciences (formerly Google Life Sciences) creating a variety of solutions for evidence generation, care delivery and care management (including end-to-end digital platforms for clinical research, precision analytics and virtual care models).[96]

These tech companies are supporting a move to personalised and consumer-driven healthcare, altering patient experience by enabling home and portable diagnostics and leveraging existing market capabilities to disrupt healthcare (see Figure 24).

Figure 25. How consumer technology companies are disrupting healthcare



Source: Deloitte analysis.

There are some areas in which diagnostics companies alone can drive adoption of technologies, such as robotics, but there are others (such as virtual reality) where they would benefit from partnering with a consumer technology company. Such partnerships would enable diagnostics companies to learn from the engineering expertise of tech companies and their knowledge of customers and enable them to respond more effectively to end-users' needs. A meaningful exchange of expertise would help diagnostics companies to develop a stronger sense of consumer behaviours and how to make more effective use of data.

It could also help consumer technology companies to gain a deeper understanding of healthcare and improve their credibility with clinicians. Diagnostics companies that successfully integrate some, or all, of these services will be pivotal in helping healthcare providers democratise when, where and how care is delivered. It will also help the move towards more personalised and preventative services.

How diagnostics companies can transform future clinical pathways

Given the acceleration of advances in science, technology, miniturisation, and advanced analytics, Deloitte believe the future of diagnostics is interegral to the future of health and this co-dependency will transform the future of diagnostics and in turn help realise the future of health.

We have envisioned how three patient pathways might look in the future, and how these would contribute to a more predictive, preventative, personalised and participatory (4P) future of health.

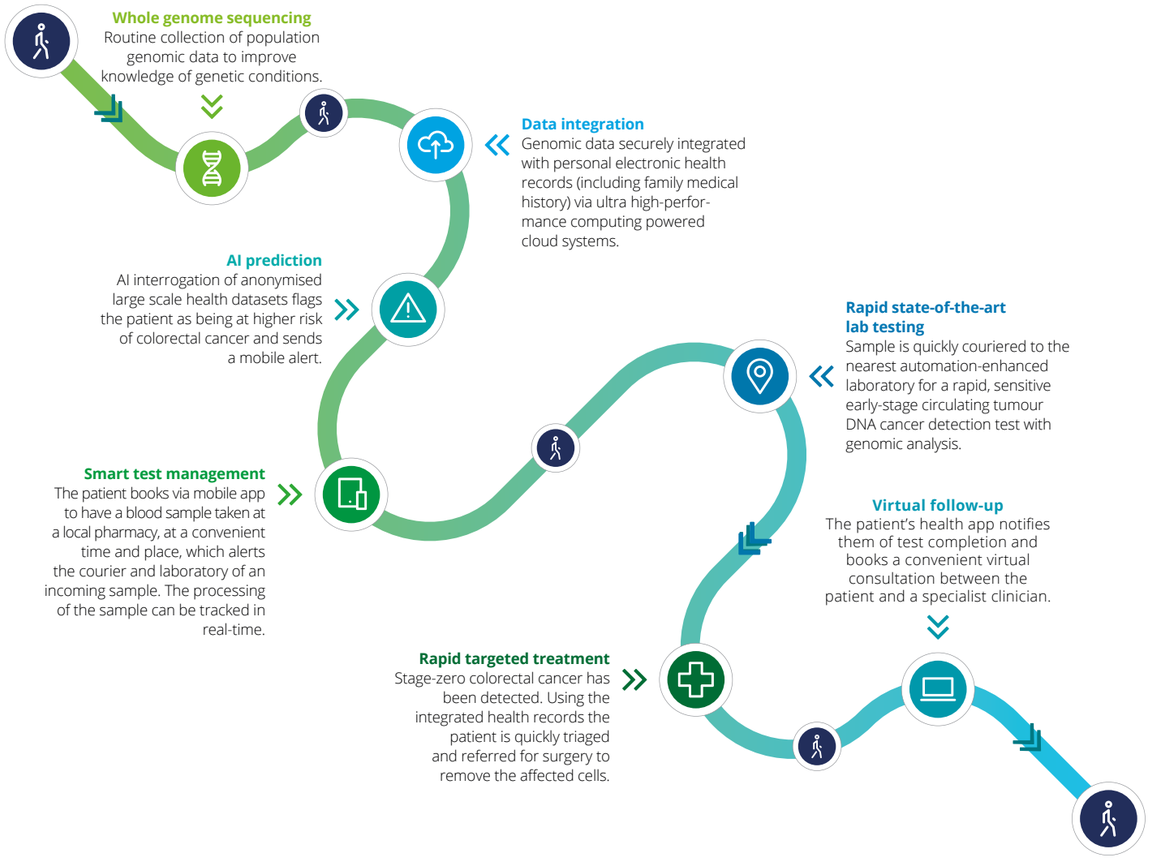
Pathway 1. Disease prediction and screening of colorectal cancer

Current pathway challenges

- As with other screening services, colorectal cancer screening programmes across Europe have variable performance and participation rates and eligibility criteria for screening limits access to these tests.[97]
- Colonoscopy services are facing large and increasing patient backlogs with delays in cancer diagnosis resulting in more complex treatments, poorer patient outcomes and higher costs.[9899]

An example of innovation today

- **ColoAlert (Mainz Biomed)** – A self-sampling colorectal cancer test kit that patients use at home and return to a local laboratory for processing via mail. This test advances current faecal immunochemical test (FIT) technology with the addition of PCR-based detection of tumour-specific DNA biomarkers, aiming to detect cancer at a far earlier stage.[100]



Source: Deloitte analysis.

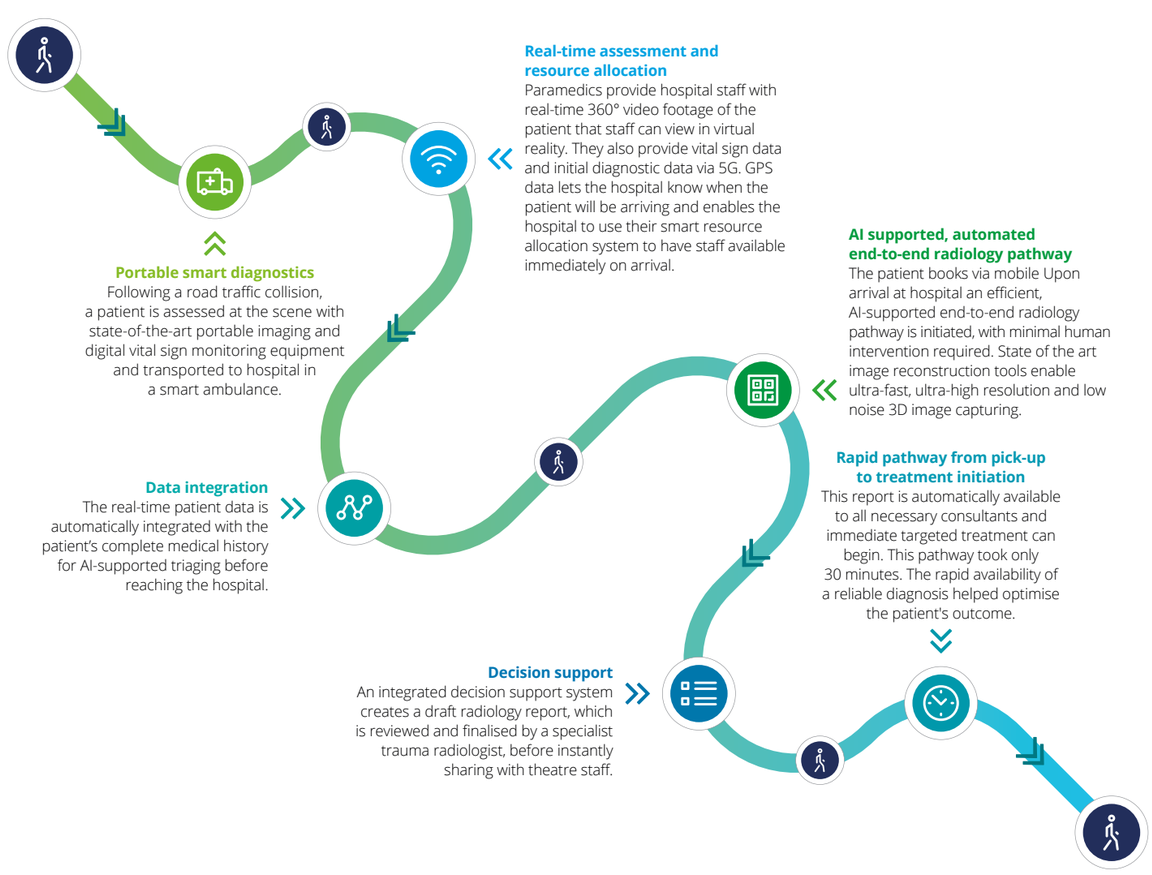
Pathway 2. Improving the efficiency and effectiveness of diagnosis for trauma patients

Current pathway challenges

- Ambulance service response times are getting longer and improvements in service efficiency are needed.[101] Manual data capture and poor data flow between ambulances and hospitals have a negative impact on efficiency.[102]
- To optimise patient outcomes, major trauma guidelines state that radiology reports of 3D imaging for chest trauma, haemorrhage and spinal injury should be available within one hour of the scan.[103]

Example of innovation today

- **Vodafone and 5G** – Connected ambulances: to prevent treatment delays upon arrival at hospital, Vodafone 5G is developing 'connected ambulances'. This is currently being used in Milan to enable paramedics to share real-time images, vital signs data and initial diagnostic data, and review healthcare history (with the support of augmented reality). Advanced treatments can be started in the ambulance before reaching the hospital. Trials of 5G ambulances are also currently taking place in the UK, Spain and Ireland.[104]



Source: Deloitte analysis.

Pathway 3. Chronic heart failure remote patient monitoring

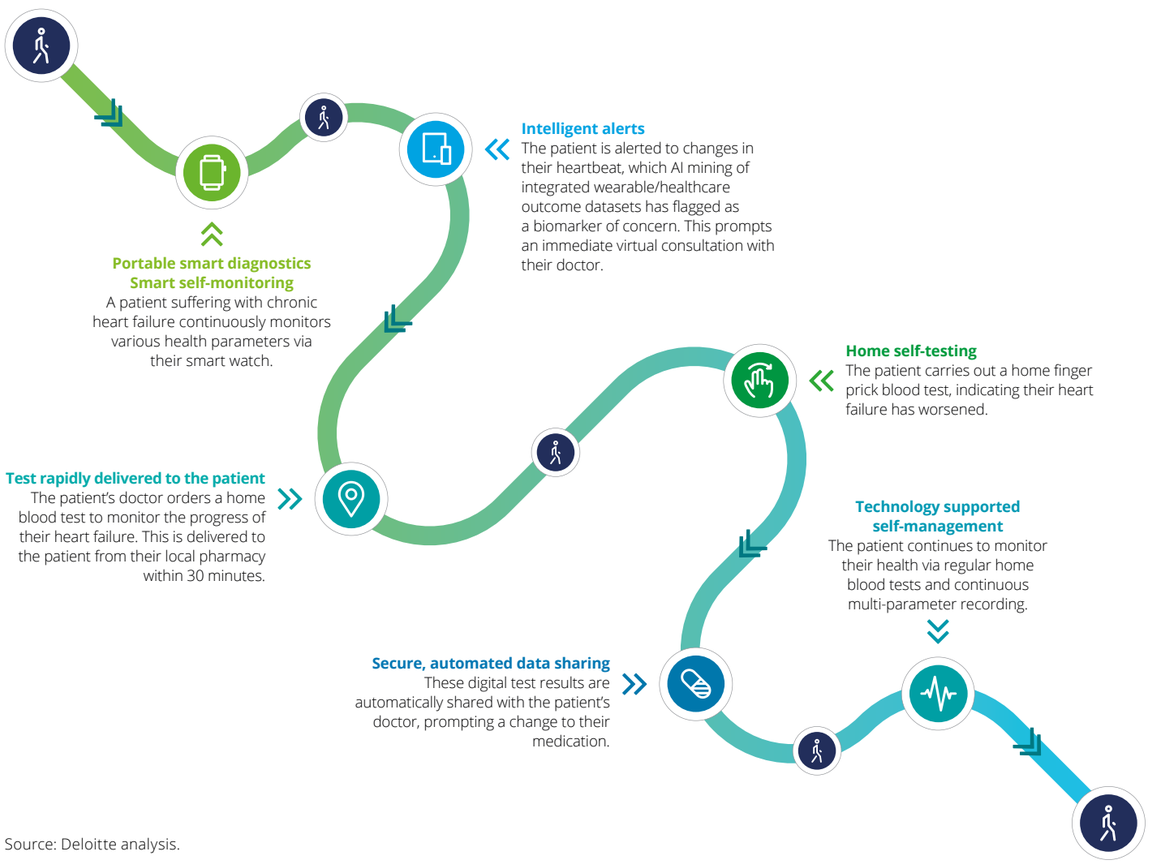
Current pathway challenges

- Patients with heart failure are often diagnosed late. They have high rates of hospitalisation and readmission, due in part to a lack of use of reliable remote monitoring technology to provide early warnings.[105] Currently standard practice relies on frequent clinical assessment to determine the state and progression of the condition and the prescription of medication based on clinical guidelines. This is inefficient and relies on episodic data. [106]
- Blood tests for heart failure such as the brain natriuretic peptide (BNP) test can take as little as 15 minutes. However delays are incurred as the tests are carried out by GPs or at outpatient laboratories/clinics using venous blood samples as standard.[107]

Example of innovation today

- **Finger-prick home testing (Medichecks)**[108] – Medichecks provide an increasing library of at home tests for health monitoring, requiring only a finger prick blood sample. Current tests range from advanced thyroid function blood tests to various vitamin and hormone tests.

The beneficial impact of telemonitoring comes from daily transmission of weight, blood pressure, heart rate, heart rhythm, oxygen saturation and self-related status to the clinician. Patients also receive education in heart failure and monthly structured telephone interviews. In the study, adherence by the 975 patients in the study was high, compliance was 70%, and there were reductions in unplanned hospitalisations and mortality.[109]



Source: Deloitte analysis.

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Conclusions and actions for stakeholders

The pandemic has accelerated changes to both diagnostic pathways and technology adoption. Innovations are improving access to diagnostics and transforming care pathways across Europe. New technologies and models of diagnostic service delivery designed around the patient, to optimise access and outcomes, are altering care pathways and resulting in a shift in the location of diagnostic services and decentralisation of service delivery. The pandemic has accelerated a paradigm shift in diagnostics, heralding an era of revolution in terms of its scope and capacity and in opportunities for reducing healthcare costs and driving economic growth. The pandemic has demonstrated that a crucial way forward, to handle the growing demand for healthcare, is improved access to diagnostics, including point-of-care testing, self-testing kits, genomic testing, digital diagnostics, and the implementation of artificial intelligence (AI)-based analytical solutions, and to use the information generated to better align demand to supply of healthcare services.

The future is one in which diagnostics are crucial drivers of the future of health, where care is predictive, preventative, personalised and participatory:

- **Predictive and preventative:** The pandemic has made us even more aware of the importance of a healthy lifestyle. For many people in Europe, 'lifestyle' is monitored widely by consumer wearables, smart watches and smart scales. But platforms that offer both lifestyle advice and diagnostic services are few and far between. Putting the two together will provide personal, tailored advice and treatments. When it comes to chronic diseases, such as diabetes, the sooner people are aware of the problem, the faster they can change their lifestyle, and the likelier they are to stay healthy. As the accuracy of genomic sequencing has improved and sequencing platforms have become more affordable, advances in data analytics have helped reveal hidden patterns, correlations and other insights. Technology is enabling much higher throughputs and low-cost solutions. Many consumers are also consenting to make their data available for research, increasing the volume of available biological data, and providing a rich foundation for the future of diagnostics. The value of these data and insights will also likely result in more spending on prevention, including investments in new diagnostic tools and platforms.
- **Personalised and participatory:** Consumers expect to live longer and enjoy healthier lives. This is leading to an increased demand for more personalised solutions, from tailor-made diets and exercise programmes to personalised pharmaceutical interventions. New research tools and technologies like proteomics are increasing scientists' understanding of human biology and disease. Personalised medicine has become more feasible because of genetic diagnoses and automation in healthcare. We may soon be able to predict chronic diseases such as cancer, cardiovascular problems, and type 1 diabetes. Next generation sequencing (NGS) will enable us to understand every unique human genome and how it affects the individual patient. New diagnostic tools, like liquid biopsy, are making possible the earlier detection and more targeted treatment of some of the most serious diseases. Moreover, new business models are bringing diagnostic tests to patients at home. People will finally 'own' their health – because prevention and treatment can be personalised. This will increase the opportunities for diagnostic companies to provide healthcare monitoring and support services.

All these developments have the potential to transform the industry. They have ramifications across the value chain, affecting patients, providers, clinicians, scientists, laboratories and the biopharma industry. Diagnostics companies need to decide which role they want to play in the future of health and how they want to participate in emerging fields to build winning strategies. In healthcare systems, diagnostics need to be placed at the centre of disease and patient pathways, to detect diseases as early as possible and provide accurate guidance to the right treatment, improving the cost-effectiveness of healthcare and, importantly, patient outcomes.

Actions for the diagnostics industry

To realise the future of diagnostics, there are a number of actions that need to be taken today.

Addressing interoperability and embedding data security requirements in diagnostic design

- interoperability is arguably the biggest challenge for diagnostic companies including complying with emerging national and international standards and protocols around the exchange and use of data
- create an integrated governance framework and consent protocols on accessing and using healthcare data
- adopt a 'security by design' approach to embed data security and cyber mitigation strategies from the outset and establish real-time monitoring, cyber threat modelling and analysis, threat mitigation and remediation
- develop key principles of data management and consent that give patients control over their own data, including the right not to share

- ensure the company's IT infrastructure can handle and process the data and insights from connected diagnostic devices and communicate this effectively to providers and clinicians to help build trust in the device
- adhering to data standards
- prioritising data privacy, security and trust.

Developing a clear regulatory approval route map

- take a proactive and well-planned approach, including having early discussions with regulators about the intended use and benefits of new products and advocate for the creation of target product profiles (TPPs)
- if an innovative product is to be successful, companies need to build engagement with regulators into their innovation model and involve clinicians and patients in product design
- connecting with HTA bodies who are increasingly joining up with regulators to provide support back to industry
- understanding the requirements of the regulatory approval process and developing a clear route map to approval
- on DTCs, find a suitable balance between rapid technological development and the deliberative and cautious nature of the new regulations, and the risks will need to be carefully assessed by regulators, clinicians, and researchers to optimise benefits and minimise harm to the public.

Aligning with patient and provider needs to improve adoption of diagnostics at scale

- diagnostics are almost always designed for a specific application, adding connectivity to a device allows data to be generated on a patient's condition and the effectiveness of the health care providers operations, being able to quantify, contextualise and communicate these interactions enables industry to provide solutions that deliver value to all health care stakeholders
- develop a deep understanding of the end user and create business models and scenarios that demonstrate how new and existing diagnostics not only improve patient outcomes but also create value for the health system
- co-develop diagnostics with patients and clinicians to understand and address areas of unmet need collaborate with end-users to improve their understanding of new technologies
- ensure that the devices are intuitive and easy to use and, where necessary, provide training and support to staff to embed the skills needed to optimise the use of the technology
- adopt a 'sustainability by design' mindset
- consider how to design devices for use in non-traditional locations that can integrate effectively into new care pathways, bearing in mind the expectations of clinicians in supporting shifts in location and the opportunities to collaborate to develop new care pathways

- to remain competitive diagnostics companies need to establish a new, digital-first skill set, including employing data scientists, AI experts and multidisciplinary talent from creative and scientific backgrounds. Accessing this talent will require more resourceful recruitment and retention strategies, including collaborations and partnerships with a diverse range of existing and emerging players, especially academia, data-first tech companies and innovative new start-ups.

Developing a clear funding and reimbursement strategy

- develop a strong evidence base to be able to demonstrate the added value of both new and enhanced products. Different types of diagnostic devices and products will require different funding models and progress will require companies to work in new ways to share risks and rewards more effectively
- map the differences in reimbursement pathways across geographies
- create a clear vision about a product's value proposition and how it compares to existing solutions in terms of cost and effectiveness
- develop a health economic case for investment based on real-world evidence that demonstrates the business case for change.

Preparing the supply chains of the future

- take actions to improve supply chain resilience such as planning, forecasting and improving stock reserves, including early planning for alterative components and enhanced supply chain visibility and traceability
- understand and prepare now for net zero ambitions that require diagnostic device suppliers to comply with new standards.

Actions for the healthcare system (including payers and providers)

Improving signalling about what is needed

- provide better signalling about what healthcare systems' priority needs are
- collaborate with industry to design solutions to meet those needs
- provide education and training to their workforce and other end users on the use and benefits of innovations in diagnostics such as AI, genomics, and digital.

Improving digital infrastructure and maturity

- for interoperability to support productivity, there is a need to develop open platforms, based on open data standards; and to provide clear guidance to industry on how data will be made available to each another
- establish a common platform to integrate, share, aggregate, and view data to drive both clinical and operational value and which link disparate sets of data within health care organisations, including diagnostic data, is central to achieving connectivity at scale
- mine, manage and apply advanced analytics to the vast array of data from medical grade wearables, connected imaging devices and patient monitoring devices is a key to deriving value from the IoMT. The insights generated by linking connected diagnostic devices and health data sets can play a key role in aiding health systems to reduce costs and improve quality, identify populations at risk, connect with consumers and better understand performance.

Agreeing new funding and reimbursement models

- develop reimbursement models based on VBC outcomes and risk guarantees, with the prioritisation of technologies for which there is an acknowledged need and by evolving the evolution of existing payment systems of both public and private payers
- agree to provide more parity of investment in diagnostic technologies to reflect the value they can bring to improving access to and earlier diagnosis and in improving prevention to reduce downstream healthcare costs
- provide more effective signals to private investors on healthcare needs and willingness to adopt new diagnostic technologies
- design new payment models based on collaborations, and which reward all partners for health outcomes and better management of health and wellness
- establish a European-wide ecosystem to support manufacturers in navigating and obtaining funding for the development and launch of their products in Europe.

Actions for regulators and HTA bodies

Improving communication with innovators

- the increased costs of diagnostic technology development, increased clinical evidence requirements and bottlenecks in the capacity of notified bodies are real and present challenges for the industry, regulators need to improve communication and cooperation in developing a clear route to regulatory approval and prioritise regulatory capacity building.
- the rapidly evolving regulatory landscape is causing uncertainty, resulting in a need for regulators to provide better guidance and direction on their expectations, including creating target product profiles (TPPs)
- regulators are also themselves trying to work out what their new roles are. Fixing this problem and improving communications between regulators and innovators should be a priority and help to provide more certainty.

Promoting and accepting real world evidence

- the short lifecycle and speed of incremental improvements of many diagnostics makes evidence generation via traditional randomised control trials difficult, a transition to the acceptance and use of real-world evidence will be essential.
- the evolving role of diagnostic companies in providing value across the entire continuum of healthcare from screening, diagnosis and prognosis to deliver more predictive, preventative, personalised and participatory model of care will need HTAs to take a more flexible and inclusive approach to assessment.

Glossary

5G	The fifth generation of mobile networks, delivering higher speeds and lower latency than previous generations.
Algorithmic bias	An algorithm is a sequence of software instructions for performing a process or making a calculation. Algorithms are created by humans. Algorithmic bias can lead to inappropriate distribution of healthcare resources or to the use of technology that does not work for one community as it does for another – for example a skin cancer detection app that is less likely to make an accurate diagnosis for patients of colour. Ethical evaluation of digital measurement products requires attention to algorithmic bias.
Artificial Intelligence (AI)	Machines/algorithms that mimic the cognitive functions typically associated with humans, such as learning and problem solving.
Augmented reality	Technology that combines real world images with computer-generated images and information to provide an interactive experience of a real-world environment. The objects that reside in the real world are enhanced by computer-generated perceptual information, sometimes across multiple sensory modalities, including visual, auditory, haptic, somatosensory, and olfactory.
Biomarkers	Biomarkers are used to identify certain diseases and are one of the main approaches to clinical diagnosis. Biomarkers are 'any substance, structure, or process that can be measured in the body or its products and influence or predict the incidence of outcome or disease'. This includes nucleic acids, proteins, certain metabolites and hormones. According to their type, biomarkers can provide preventive, diagnostic, prognostic, or therapeutic response related information. Biomarkers are extremely important in oncology but also can detect thrombin in the blood, neurodegenerative and cardiovascular disease, and sepsis.
Biosensors	Analytical devices, preferably small, that combine a biological element (antibodies, nucleic acid, enzymes) with a physiochemical component generating a measurable signal (for example electrical) to detect a biological analyte.
Biosensing platforms	Sensors that use different biorecognition elements such as antigens, DNA, RNA, or enzymes) to cause a detectable response when the target analyte is present in a sample (of tissue, blood, urine, etc). This detectable response can be an electrochemical, optical or mass-based change for example. Liquid biopsies are one example, gaining traction due to being minimally-invasive, easier to obtain and carring less risk than tissue biopsies, traditionally required for many tests.
Blockchain	A secure immutable shared ledger technology used to accurately record and monitor data transactions
Cloud computing	On-demand computing services (such as data storage and processing) delivered via the internet. These services can be used to store securely and share electronic health records and diagnostic data.
Computed Tomography (CT)	This medical imaging procedure involves rotating X-ray beams around a patient's body to obtain computer-generated cross-sectional image 'slices' of the body.
Cyber security	The protection of connected devices and electronic data from theft, loss or damage. Reducing the risk of cyber attack is critical to ensuring the safety of personal data collected, stored and analysed on diagnostic devices and associated computer systems.
Digital infrastructure	The combination of virtual and physical technologies that enable interoperable, connected health information. This includes hardware (such as computer systems, connected devices and data centres), connectivity (Wi-Fi, 5G, etc), safe data storage (including cloud systems), access to health data, and safe data sharing (including interoperable electronic health records).
Digital medicine	Products such as digital diagnostics, digital biomarkers, electronic clinical assessments tools, remote patient monitoring (RPM) and decision support software.
Digital therapeutics (DTx)	Software products (such as mobile apps) used in the treatment of medical conditions to deliver clinical outcomes. Clinical evidence and real-world outcomes are required for all DTx products and are commonly regulated under SaMD frameworks.
Digital twins	A dynamic virtual model of a physical object or system.
Direct-to-consumer (DTC)	A diagnostic device that is sold directly to the patient (consumer) rather than to a healthcare system or provider organisation. Current examples include at home blood tests or self-monitoring devices.
European Commission	The European Commission is the executive body in the European Union that determines the EU requirements for medical device regulation.
European databank on medical devices (EUDAMED)	A European IT system introduced by the MDR and IVDR to provide access to medical device and product lifecycle data, providing a picture of the lifecycle of medical devices available in the EU. It integrates different electronic systems to collate and process information about medical devices and related companies (e.g., manufacturers); aiming to enhance overall transparency, including better access to information for the public and HCPs and coordination between EU Member States.

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Fast Healthcare Interoperability Resources (FHIR) standard.	FHIR was launched in 2014 to improve interoperability, enhance efficiency of communication and streamline implementation, providing easily understood specifications and enabling developers to capitalise on common web technologies (application programming interfaces or APIs)). Clinicians can share patient data more efficiently to speed up decision-making and patients can take greater control of their health by accessing medical information through consumer-friendly apps running on smartphones, tablets and wearables.
Genomics	The study of an individual (or organism's) complete set of DNA and all the genes it contains. This contrasts with genetics, which studies individual genes. Whole genome sequencing is used to identify and understand the role of genes in disease, including predicting disease and treatment responses.
HL7 (Health Level Seven International	HL7 is a not-for-profit organisation dedicated to developing standards for exchanging, integrating, sharing, and retrieving electronic health information. It works by providing a language for communication between distinct systems, such as electronic medical record (EMR) systems, hospital information systems, radiology and picture archiving systems, laboratory information systems, and billing systems. In 2020 the U.S. Center for Medicare & Medicaid Services (CMS) finalised a mandate for the use of FHIR by mid-2021. There is also a clear momentum for using FHIR for mobile healthcare apps.
Health technology assessment (HTA)	A systematic evaluation of a health technology, used by countries to inform best practice of care, reimbursement and procurement.
In vitro diagnostic (IVD)	Diagnostic tests that involve human samples (such as urine or blood) and are not conducted on the human body itself.
Internet of Things (IoT)	A network of connected smart devices that can communicate with each other
Lateral Flow Test	A diagnostic device that relies on the flow of liquid along a pad. These are simple, rapid tests that detect the presence of a target molecule (often an antigen) using reactive molecules (antibodies) on the surface of the pad.
Liquid biopsy	Sampling of non-solid tissue, most commonly blood. This has applications in future cancer diagnostics for example, where circulating tumour DNA can be detected in the blood.
Machine learning (ML)	Software that uses advanced statistical methodologies to derive insights from complex datasets via an iterative learning process.
Magnetic resonance imaging (MRI)	A medical imaging procedure that creates detailed images of internal organs using strong magnetic fields and radio waves. Unlike many other medical imaging procedures, it does not involve ionising radiation.
Medicines and Healthcare products Regulatory Agency (MHRA)	A government agency responsible for the regulation of medicines, medical devices, and blood components for transfusion in the UK.
Nanotechnology	Technology that relies on the unique properties of nanosized particles (10^{-9}m).
Notified body	Independent organisations designated by European member states to assess the conformity of medical devices and in vitro diagnostics to their respective regulations.
Point-of-acre (PoC) testing	Testing that is carried out at or close to the patient.
Polymerase chain reaction (PCR)	A process that creates billions of copies of a DNA from a small sample, commonly used in the detection of infectious diseases.
Positron emission tomography (PET)	A medical imaging procedure used to assess tissue and organ function. A radiotracer (a substance which emits radiation) is injected into the bloodstream and the PET scanner detects where this does and does not collect, in order to assess body functions.
Quantum computing	Computing that uses quantum mechanics to exponentially improve performance.
Real world data/evidence (RWD/RWE)	The evaluation of data generated during routine use of the diagnostic, in its intended environment, by its intended operator, and testing a diverse group of the intended patient population.
Software as a medical device (SaMD)	Software with an intended medical purpose, acting either as a standalone device or connected to/driving another medical device.
Target product profile (TPP)	A set of specific requirements for a product, indicating performance standards such as required sensitivity, specificity, and usability levels.
Virtual reality	Technology that immerses the user in a computer-generated environment.

Methodology

The findings in this report are derived from an extensive literature review, semi-structured interviews with 40 stakeholders from across the diagnostics ecosystem, survey responses from 250 companies with at least one diagnostic product in their portfolio, survey responses from 751 front-line clinical staff (clinicians) and insights from Deloitte colleagues across the world.

Our research has aimed to examine how innovations are improving access to diagnostics and transforming care pathways across Europe and the barriers and enablers to progress that the industry faces.

Diagnostics companies survey

Our survey of 250 companies with at least one diagnostic product in their portfolio covered 19 countries across Europe (Figure 26). It was conducted on our behalf by iResearch Services (iResearch). Our diagnostic company survey respondent demographics are shown in Figure 27.

Figure 26. Geographical spread of diagnostics company survey respondents

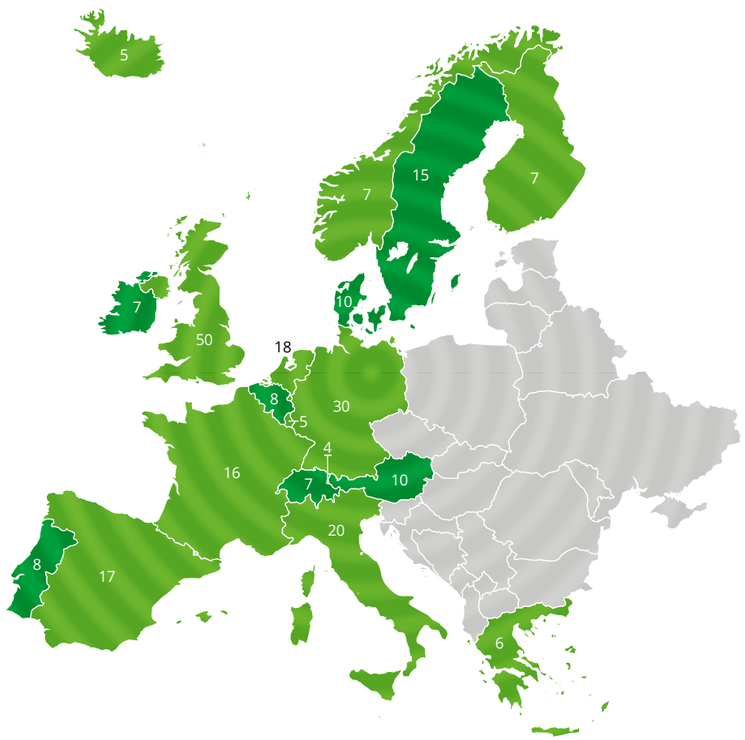
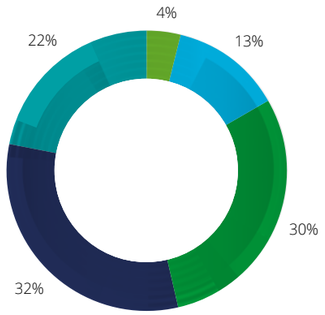


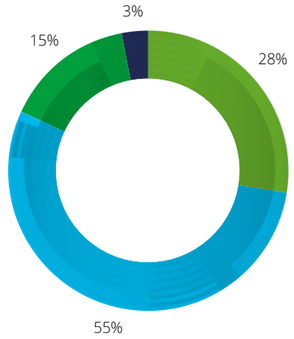
Figure 27. Diagnostics company survey respondent demographics

ORGANISATION SIZE



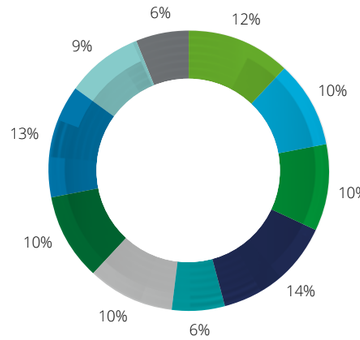
- Micro (1-9 employees)
- Small (10-49 employees)
- Medium (50-249 employees)
- Large (250-1000 employees)
- Very large (more than 1000 employees)

NUMBER OF COUNTRIES OPERATE IN



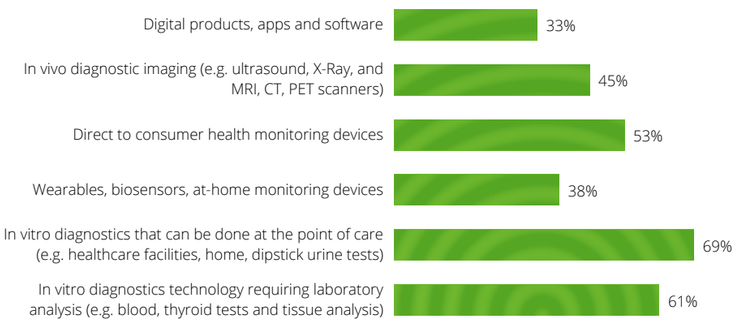
- 1
- 2-5
- 6-10
- 10+

ROLE



- Chief medical officer (CMO)
- Chief clinical officer (CCO)
- Chief experience officer (CXO)
- Chief operating officer (COO)
- Chief commercial officer (CCO)
- Chief clinical information officer (CCIO)
- Chief procurement officer (CPO)
- EVP/VPs product development
- Director of clinical informatics
- Head of technology

TYPE OF MEDICAL DEVICE



Clinician survey

Our survey of 751 clinicians across Europe covered six countries across Europe (Figure 28). It was conducted on our behalf by Sermo. Our clinician survey respondent demographics are shown in Figure 29.

Figure 28. Geographical spread of clinician survey respondents

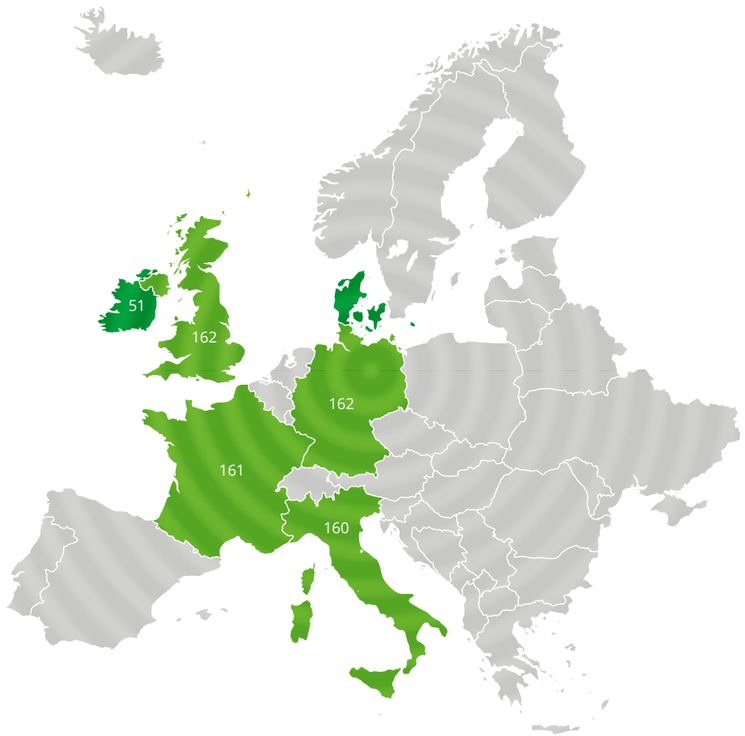


Figure 29. Clinician survey respondent demographics

External stakeholders interviewed

Name	Organisation	Role
Alex Brecciaroli	Shared Labs Europe	Managing Director
Andrey Bychkov	Kameda Medical Center	Director of Digital Pathology
Professor Carole Longson	Independent	Senior Advisor Life Science Policy, HTA and Market Access
Christopher Breyel	MedTech Europe	Director of Member Relations & MedTech Europe Events
Costa Philippou	Medilink Midlands	Former Business Development Manager
David Wells	Institute of biomedical science	CEO
Dhalveer Dhami	Illumina	Chief of Staff to the CCO
Dimitris Grammatopoulos	Warwick University and UHCW NHS Trust	Professor of Molecular Medicine and Consultant in Clinical Biochemistry
Eleanor Charsley	ABHI	Director, Government Affairs
Fernand Goldblat	BD	VP GM Integrated Diagnostic Solutions
Fiona Maini	MediData	Principal Global Compliance and Strategy Manager
Graeme Tunbridge	BSI	Senior Vice President Global Regulatory and Quality, Medical Devices
Guido Baechler	Mainz Biomed	CEO
Jean-Noel Bouillon	MedTech Europe	Director IVD member relations
Jeremy Stackawitz	Senzo	CEO
Jesus Rueda Rodriguez	MedTech Europe	Director General Strategies, Special Projects and international affairs
Krishan Ramdoo	Tympa Health	CEO and ENT Specialist
Margaretta Colangelo	Jthereum	Co-founder
Mark England	Health Navigator (HN)	CEO
Martin Witte	TUV SUD	Senior Director Global Strategic Business Development
Mathias Goyen	GE Healthcare	Chief Medical Officer EMEA
Matt Nelson	Illumina	Senior Director, Companion Diagnostic Partnering
Michael Kipping	Element Materials Testing	Director, Medical Technologies EMEAA
Min Bhogaita	MyPulse	Business Development Associate
Neil Anderson	Consultant Clinical Biochemist and Chief Scientist	University Hospitals Coventry and Warwickshire
Nicholas Van Mele	MedTech Europe	Director General Operations & Services
Nishan Sunathares	ABHI	Managing Director, Diagnostics
Oyinkan Donaldson	Lifescan	Vice President, Regulatory Affairs
Paddie Murphy	PLMCS	Director and founder
Paul Oladimeji	Novacyt	Group Head of Research & Development
Petra Zoellner	MedTech Europe	Senior manager IVD
Pierre-Alexandre Fournier	Hexoskin	CEO
Raj Kohli	MyPulse	Co-Founder & Chief Clinical Innovation Officer
Rob Howes	Rosalind Franklin Laboratory	Director
Sam Rodgers	MediChecks	CMO
Sarah Mee	GSK	Director, Commercial Pipeline Policy & Advocacy Global Corporate Government Affairs & Policy
Stephen Lee	ABHI	Director of Diagnostics Regulation
Sylvain Morgeau	Biomerieux	Head of Strategy
Zlatomira Chomakova	MyPulse	Senior Brand & Marketing Executive

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