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Reforming diagnostics
Turning challenges into enablers

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Deloitte Centre *for* Health Solutions

Contents

Foreword

Welcome to this Deloitte Centre for Health Solutions report, *Reforming diagnostics: turning challenges into enablers*; a companion report to our report – *The future of diagnostics: technology driven personalised and preventative healthcare in Europe*. This companion report explores how the key challenges identified through our primary research (surveys, interviews, and literature reviews) can be turned into enablers to ensure a more productive and sustainable future for the industry.

Diagnostics are crucial to almost every clinical interaction with a wide range of diagnostic devices and tests playing a pivotal role across the entire healthcare continuum from screening, detection and prognosis to patient stratification and condition monitoring. Diagnostic tests impact most healthcare decisions, supporting clinicians to provide an accurate diagnosis and prescribe 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 the shift from reactive, episodic treatment, to proactive, preventative care.

However, diagnostics companies face numerous challenges in designing, developing and gaining adoption of new products. These challenges include shortcomings in healthcare's digital infrastructure (such as interoperability and connectivity), meeting the new regulatory requirements, obtaining enough clinical evidence on outcomes, and difficulties accessing funding and reimbursement. Consequently, it can take eight to ten years to bring a new product to market and some never make it.

This report provides several suggested frameworks, examples of innovative technologies and case studies that demonstrate how these challenges can be turned into enablers; and help the diagnostics industry realise its potential to play a crucial role in the design and implementation of new diagnostic care pathways. These enablers can also help the health system move from volume to value-based care and deliver a future in which diagnostics are crucial enablers of more predictive, preventative, personalised, participatory (4P) care.

As always, we welcome your feedback.

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Reforming diagnostics | Turning challenges into enablers

Challenges to the reform of diagnostic services

Diagnostics companies face significant challenges in bringing innovative new products to market. The process from identifying the need for a new product, through development, regulation and adoption, to building a market for the product, can take many years. However, understanding how to tackle these challenges and turn them into enablers can help the diagnostics industry play a crucial role in the design and implementation of new diagnostic pathways and in helping to deliver improved clinical outcomes.

Most countries in Europe have identified the need for a more radical approach to investment in and reform of their diagnostic services. This need was highlighted during the COVID-19 pandemic. However, the pandemic has also provided a much-needed boost to the transformation of diagnostics. There have been many beneficial changes such as greater use of virtual consultations, new types of diagnostics and changes in the location of where services are delivered, with more at-home direct-to-consumer (DTC) tests, point of care (POC) imaging and in vitro diagnostic (IVD) services.

Our main report, *The future of diagnostics: technology driven personalised and preventative healthcare in Europe*, explores the evolving role of diagnostics in shaping new clinical pathways and how the adoption of disruptive diagnostic technologies is a crucial driver of more predictive, preventative, personalised and participatory (4P) care. It presents our primary research findings from our survey of 250 diagnostics companies (which have a diagnostic product in their portfolio), our survey of 751 clinicians across Europe (nurses, doctors and healthcare professionals) and interviews with key stakeholders. It highlights the main challenges facing the diagnostics industry and clinicians, and also some of the opportunities for improvement: importantly it explores what the future of diagnostics might look like in five to ten years' time.

This is a companion report to the main report and explores how the overarching challenges (see Figure 1) can be turned into enablers, to build a more productive and sustainable future for the industry. This report can be read either as a stand-alone publication, or in conjunction with the main report.

Figure 1. 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.

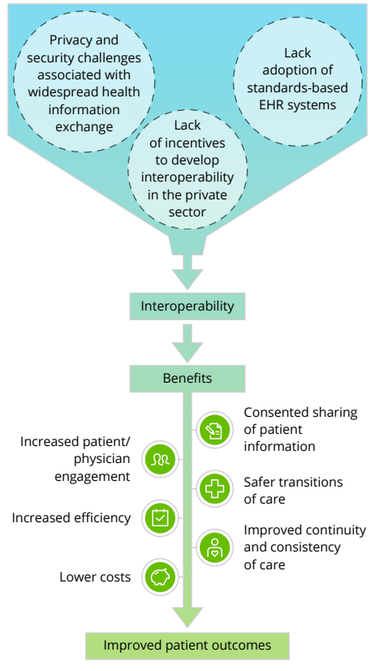
Digital infrastructure: improving interoperability and connectivity

The respondents to our survey of diagnostics companies identified shortcomings in the digital infrastructure of healthcare (specifically, its interoperability and connectivity) as the top challenge they face in bringing a new diagnostic device to market. Interoperability is the extent to which systems and devices can exchange and share data. It relies on diagnostics companies being able to ensure their products can establish connectivity and communication with healthcare systems including integrating into their electronic health records (EHR), to help streamline clinical operations and workflow management and improve patient care, even from remote locations.[1]

Our 2018 report *MedTech and the Internet of Medical Things* identified serious barriers to achieving the interoperability that MedTech companies needed for effective deployment of their connected products and devices (see Figure 2). The report also identified systemic technical challenges, such as creating an integrated data governance framework and obtaining consent for access to healthcare data. It concluded that for interoperability to work effectively, the direction of travel needed to be towards open platforms, based on open data standards, and for payers, providers, and technology vendors to come together and share data more effectively.[2]

Figure 2. Addressing healthcare interoperability challenges

Interoperability can provide numerous benefits to health care stakeholders



Key actions healthcare stakeholders should consider when tackling the interoperability challenge

Source : Adapted from Deloitte report MedTech and the Internet of Medical Things: how connected medical devices are transforming healthcare.

"Partnerships are key to modernise the digital infrastructure which will enable diagnosis closer to patients, data sharing, and speed up how diagnostic information is used to guide treatments."

Industry Body

There have been some improvements since 2018, for example in the digital maturity of European healthcare systems (with an increase in the number of digital hospitals), and the wider adoption of international standards like the Fast Healthcare Interoperability Resources (FHIR) standard (widespread adoption across Europe is expected by 2024).[3] However, there is still a long way to go. In our 2020 report *Digital transformation: Shaping the future of European healthcare,* we found a wide variation in the pace and scale of digital transformation in Europe, both within and between different countries, and identified the need for accessible and open electronic health records that are interoperable between care settings to enable diagnostic technologies to integrate readily into patient pathways.[4]

In 2021, MedTech Europe reported that insufficient interoperability continued to be a barrier to digital transformation, with a lack of agreed standards and frameworks resulting in fragmented, divergent opinions depending on specific use cases.[5] However, the general move across Europe towards value-based care (VBC) has enhanced the drive for standardised data frameworks and effective data exchange.[6]

In May 2022 the European Commission published a proposal for European Health Data Space legislation, aimed at 'addressing health-specific challenges to electronic health data access and sharing',[7] and setting out rules for data generated by Internet of Things (IoT) devices.[8] The proposed legislation would aim to improve access to data to benefit healthcare delivery (including better diagnosis) and greater innovation. A key consideration would be to harmonise the new regulation with those already in existence, such as the General Data Protection Regulation (GDPR); as well as to protect intellectual property and trade secrets.[9] [10] [11]

In April 2022, the Faculty for Clinical Informatics published draft standards and an interoperability strategy for health and care in the UK, key elements of which could be applicable to systems across Europe (see Figure 3).[12] Ultimately, the medical devices and diagnostics industry has an important role to play in shaping future legislation, to ensure that it can appropriately and safely access the medical data required to both develop innovative solutions and support the digital transformation of healthcare.

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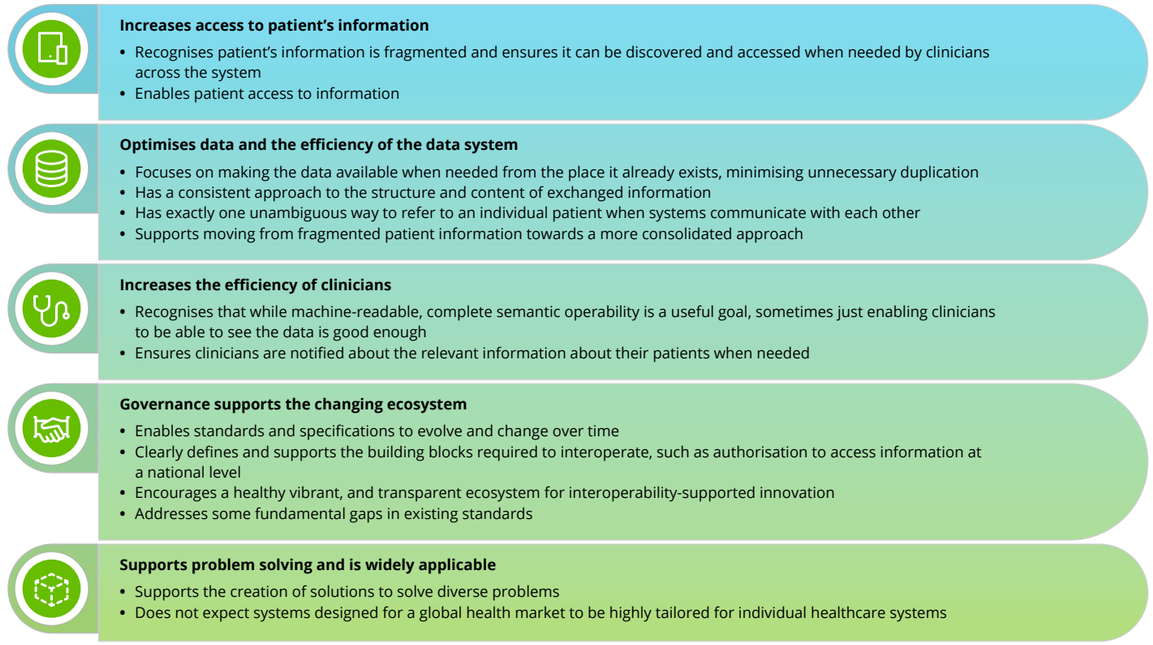
Figure 3. The main requirements for an interoperable health care system



Source: Adapted from The Faculty for Clinical Informatics – https://facultyofclinicalinformatics.org.uk/blog/faculty-of-clinical-informatics-news-1/post/how-standards-will-support-interoperability-90

As the use of many types of diagnostic products shifts into non-hospital or decentralised laboratory settings, the underpinning infrastructure is becoming a more complex challenge.[13] Improved connectivity is fundamental to effective digitalisation of healthcare; and Europe's current roll-out of Wi-Fi 6 and 5G telecommunications infrastructures, which provide major improvements in speed, latency, connection density and security, should make it well positioned to improve connectivity.[14] The benefits of 5G include enhanced network mobility, coverage and reliability, with applications in remote monitoring and smart ambulances, but deployment costs are considerably higher.[15]

Radiology is one area demonstrating the benefits of interoperability, data sharing and mature digital infrastructure, with many healthcare providers transitioning to the use of Enterprise Imaging: this is 'a set of strategies, initiatives, and workflows implemented across a healthcare enterprise to consistently and optimally capture, index, manage, store, distribute, view, exchange, and analyse all clinical imaging and multimedia content to enhance the electronic health record'.[16] Case study 1 provides several examples of how diagnostic imaging companies and enterprise platform providers are supporting imaging departments to improve efficiency and productivity by implementing modern interoperable data management systems.

"The digital infrastructure issue is not one that industry can easily solve - healthcare needs to solve it themselves or with industry stakeholders."

Life Science Policy and Market Access Expert

Case study 1. Enterprise Imaging: improving the productivity of radiology units

Radiology departments are facing increasing demand due to ageing and growing populations, long waiting lists for treatment (exacerbated by COVID-19 service backlogs) and new applications for diagnostic radiology. Radiology services are facing workforce and other resource constraints. To reduce the gap between demand and supply, and improve their productivity, they are seeking to adopt new technology including Enterprise Imaging. Enterprise Imaging systems enable multiple hospitals, radiology departments and clinicians to collaborate by uploading and accessing images on a single system, to provide coordinated care. There are many examples of this technology in practice:

- **Agfa HealthCare.** The emergency radiology unit at San Gerardo Hospital, Italy transitioned to using Agfa HealthCare's 'Enterprise Imaging' platform.[17] This supported the specific needs of this oncology and emergency imaging-focused department by providing a single, comprehensive patient imaging record and automatically retrieving previous images (via embedded interoperability protocols). It also enabled customised image views and comparisons between other imaging techniques, and supported collaboration between colleagues and departments for improved diagnosis, for example via a 'chat' function and remote reading. Further, Agfa HealthCare provided continuous support throughout the implementation of the system, including training and on-site support. Users of this solution have reported a 20 per cent improvement in efficiency, with enhanced productivity via easy access to all of the patient's images, workflow redesign and interoperability.[18]

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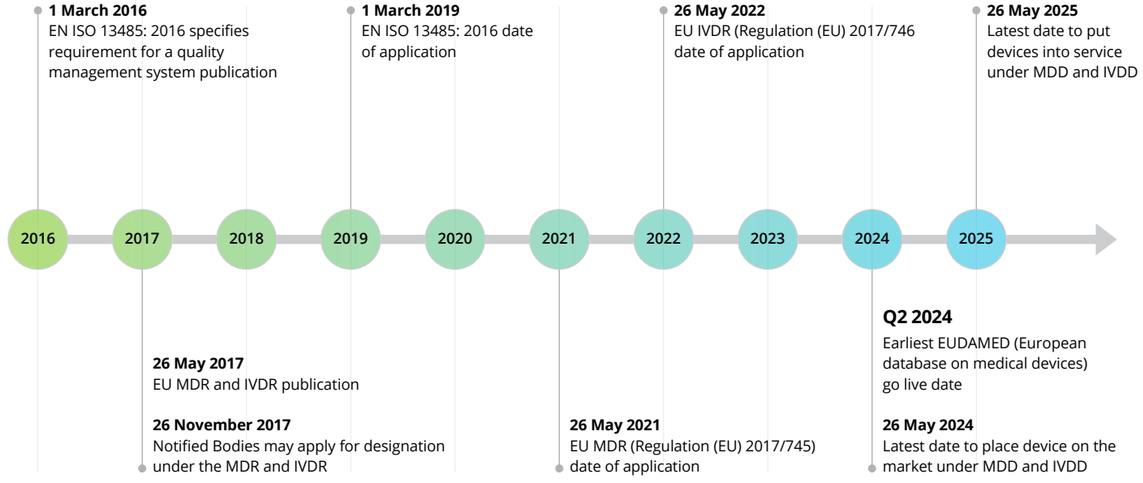
Regulation: creating flexible, collaborative approval processes

In addition to the need for compliance with legislation around data protection, sharing and access, medical devices (such as imaging machines) and in-vitro diagnostics (IVDs) are subject to strict and evolving regulation. In Europe, the implementation of the Medical Device Regulation (MDR) EU 2017/745 and IVD Regulation (IVDR) EU 2017/746 has disrupted the industry.[19] [20] Despite lengthy, and delayed, transition periods (summarised in Figure 4), the increased requirements and evolving guidance surrounding the new regulations mean that diagnostics companies face more onerous regulatory hurdles in bringing new producst to market, and in keeping existing products on the market.

All medical devices that are used to obtain a diagnosis are covered by the 2021 Medical Device Regulation.[21] The MDR maintains the previous risk-based classification of devices (Class I, IIa, IIb and III, with class III the highest risk), with some amendments to the classification rules impacting certain devices, including tighter rules around active devices intended for diagnosis in clinical situations where the patient is in immediate danger.[22] However, the IVD regulations (IVDR), which went live in 2022, have much stricter rules than previously for almost all products, bringing IVDs into a new risk-based classification system (class A, B, C or D).[23] Class D is reserved for tests with the highest risk, such as those detecting viruses), and some higher risk devices are subject to additional performance assessments by newly-established EU Reference Laboratories (EURLs).[24] Both the MDR and the IVDR are based on the intended function of the device and the 'risk posed to the health of the public and/or individual as result of a fault in the functioning of the device or incorrect test results'. The classification of the device determines the steps and evidence required to obtain regulatory approval and affix a CE mark, allowing it to be marketed in Europe.[25] [26]

Figure 4. Timeline of application for the new European medical device and IVD regulations



Source: Deloitte analysis.

"If you are a company without a notified body, that is the number one big challenge. From other companies we are hearing that the certification process is unpredictable and time-consuming, and we are still missing some key infrastructure system components."

MedTech industry body

Notified bodies (NBs) are organisations designated by European member states to assess the compliance of medical devices and in vitro diagnostics with their respective regulations. Only the lowest-risk devices are able to self-certify. The scope and application of these new regulations has resulted in a significant bottleneck around NB capacity in Europe. New certifications are required, and far greater NB involvement is mandated by the IVDR, with less ability to self-certify alongside regulating laboratory developed tests.

As of July 2022, there were 51 NBs in Europe able to certify against the previous Medical Device Directive (MDD) and 21 NBs able to certify under the previous in vitro Diagnostics Directive (IVDD); but only 31 were designated under the new MDR and seven under the new IVDR.[27] [28] [29] While these numbers are increasing gradually and further applications for NB designation are being processed, the demand for NBs is increasing significantly. For example, there was 64 per cent increase in applications for product certifications between 2020 and 2021. As legacy MDD and IVDD regimes expire in 2024/25 there is expected to be a substantial shortfall in NB capacity.[30]

Furthermore, concerns are growing over the increase in the time taken to carry out a conformity assessment, with 14 per cent of new certificates issued in 2021 taking over 19 months.[31] A MedTech Europe report in July 2022 highlighted these longer timescales, noting that the average time to certification under the MDR is 13-18 months.[32] In addition to recruiting more regulatory experts, one potential solution to this capacity problem is to automate and use AI to speed up the administrative steps in the regulatory process. A 2021 survey of the medical device and diagnostics industry conducted by Veeva MedTech found that only 17 per cent of those surveyed used a standardised, automated global process for regulatory submissions.[33] Automated digital workflows could harmonise processes, improving data collection, governance and reporting, and ultimately speed up the time to market.

Proposed future regulations like the new Artificial Intelligence Act present additional challenges to manufacturers: there are concerns that the proposals could disrupt the supply of medical devices if they are not appropriately aligned with the MDR, IVDR and GDPR.[34]

The new Health Technology Assessment (HTA) regulations present a further concern over market access.[35] However, provided that new regulations are devised in collaboration with industry leaders they could become enablers of a more supportive future.

The UK also faces a challenge from the development of new medical device and IVD regulations. Since leaving the EU, the UK regulator (the Medicines and Healthcare products Regulatory Agency (MHRA)) has required diagnostics marketed in the UK to meet the requirements for obtaining a UK Conformity Assessment (UKCA) mark for their products. The process is currently determined under the *Medical Devices Regulations 2002* but updated regulation is under development.[36] In June 2022 the UK government released plans to extend the transition times for products with UKCA or CE marks to remain on the market after the new UK regulations are implemented in 2023, easing some of the pressure on conformity assessment body capacity.[37] While it is expected that new UK legislation will align with current EU regulation, there is an opportunity to learn from the implementation of the MDR and IVDR.

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Many of our interviewees across Europe voiced concerns that the changing regulatory situation in Europe risked stifling innovation. While the EU has historically been seen as an attractive first market for diagnostic manufacturers to launch new products, the new MDR and IVDR threaten to reverse this. A specific concern is around bottlenecks in NB capacity and the increasing costs, complexity, onerous requirements, and timescales associated with the new regulations. Many of our interviewees said that this concern was causing them to look to launch their products in other markets first, such as the US. They considered that the US system is more favourable to innovation, citing the Emergency Use Authorisation (EUA) process implemented during the pandemic as a good example of a process enabling accelerated access to impactful innovations.

A similar finding emerged in a recent MedTech Europe survey of 475 medical device companies conducted in April 2022: half of the respondents said they were de-prioritising the EU market as the market of choice for first regulatory approval of their new devices, specifying the MDR as a key factor. The survey also found that companies expected to discontinue around a third of their products due to the difficulties in obtaining new approvals. However, the extended and staggered transition times given to IVD Directive devices might act to soften the number of devices which will be discontinued or not updated and the impact of the IVDR on market prioritisation for first launch is yet to be assessed.[38]

Switzerland, whose EU market access agreement for medical devices and IVDs is ending, is now looking to draft a law to allow US FDA-approved devices to be placed on the Swiss market.[39] Meanwhile, the UK sees the development of its new post-Brexit regulatory system as an opportunity to attract and retain innovation, by introducing a new innovative devices access pathway (IDAP).[40]

Lessons from the pandemic: addressing concerns that regulation will stifle innovation

During the COVID-19 pandemic many innovative technologies were developed, with accelerated approval processes and greater collaboration between businesses, regulators and government bodies shown to have a positive impact. Collaborative relationships between regulators and device manufacturers were of particular importance. Diagnostics leaders responding to our survey identified collaboration as the most important change that would help the R&D of new or enhanced products to drive the future of diagnostics, most commonly selecting: 'You are able to have early discussions and improved engagement with regulators about your proposed new products to ensure you are better able to meet regulatory approval requirements' (47 per cent).

While it is not practical for regulators to meet with every diagnostics company, early discussions and engagement could be a solution for the most innovative new products, with wider industry communication by regulators helping manufacturers of all devices to develop clear route maps to regulatory approval. Ultimately the industry just wants to know what the regulators expect and need in terms of regulatory submissions. A suggestion from our interviewees was that regulators should create target product profiles (TPPs) and clear indications of requirements for new products, which would enhance transparency and guide product development conformity.[41] In addition, prioritising capacity issues and learning from what is working well in different markets could help overcome the challenges currently being faced.

"The regulatory environment is in its shaping phase rather than being established. This presents opportunity but also an incredibly difficult territory, the sooner it can be fixed and locked the better for companies and industry. Companies want predictability and certainty."

Life Science Policy and Market Access Expert

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

Notified Body

Product innovation: improving evidence on claimed benefits

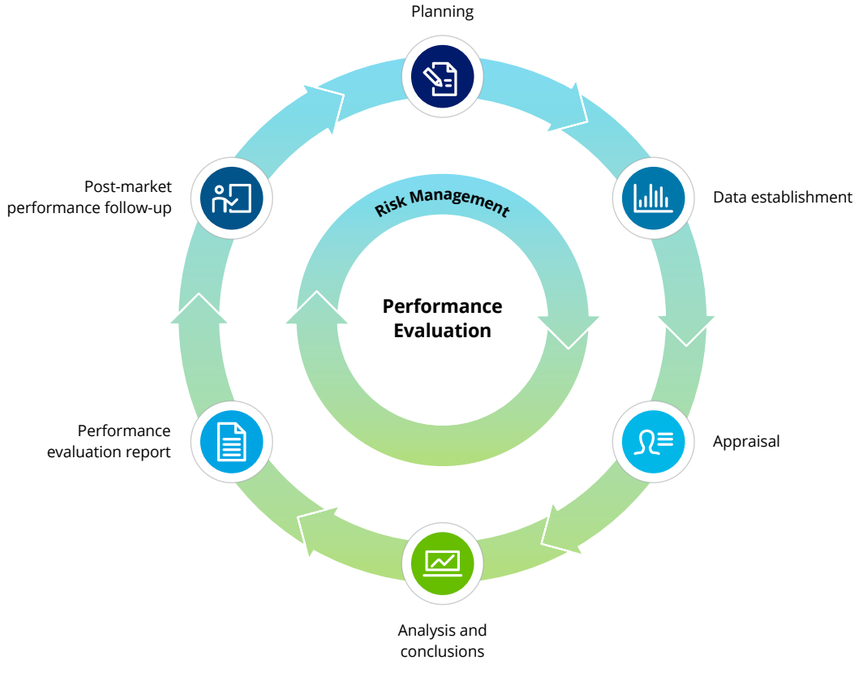
"The biggest challenge with the regulatory approval process when bringing a new diagnostic device to market is collecting all the necessary data, especially clinical data."

Notified Body

The new EU MDR and IVD regulations include enhanced requirements for clinical evidence and data generation both pre- and post-launch. For high-risk devices, including those re-classified under the new regulations, greater levels of clinical evidence will be required to secure a CE mark. Ultimately, each intended purpose and claimed benefit of the diagnostic device must be backed by evidence to satisfy regulators of the test's validity and performance. Under the MDR, devices require a clinical evaluation plan, an evaluation of clinical data and a clinical evaluation report before launch.[42]

Under the IVDR, these are called performance evaluation plans and reports. Evaluation is a continuous process throughout the lifecycle of a product, as summarised in Figure 5.[43] Furthermore, greater transparency is mandated by the new regulations: clinical investigation and performance data must be uploaded to the European medical devices database (EUDAMED).[44]

Figure 5. Overview of the performance evaluation process



Source: Adapted from figure by the Medical Device Coordination Group – mdcg_2022-2_en.pdf (europa.eu).

Generating pre-market evidence typically involves the use of clinical trials and, for IVDs, obtaining and testing clinical samples. Accessing clinical samples can be difficult, particularly for small and medium-size enterprises (SMEs).[45] While many health service and public biobanks, tissue banks and diagnostic archives exist, poor awareness of them, slow times to access samples, and governance processes (including ethics requirements) can inhibit their use.[46]

Greater effort is required to ensure that clinical samples reflect the diversity of the population it will apply to. Having the resources to do this will require greater levels of investment and improvements in the research infrastructure, including registration of biobanks, promoting their use and greater levels of collaboration between organisations to redistribute existing samples. Improved governance will be needed that supports fair access for both industry and academic researchers in developing new diagnostic products. Looking to the future, new laboratory model systems such as the use of organoids (in vitro organ models made from artificially grown cells) could become more commonplace as an accessible method of pre-clinical testing, reducing the need for some tissue collections.[47]

For digital products such as mobile applications, there are further challenges. Digital therapeutics can support multiple aspects of the patient's journey: improving prevention through supporting behaviour change; enabling remote monitoring (for example glucose tracking); gamification; and providing treatment for mental health conditions.[48] For software classified as a medical device (SaMD), the MDR and its associated device classifications and clinical evidence requirements apply (in addition to international medical device software standards).[49]

For diagnostics, this includes standalone software presenting and analysing diagnostic information, software driving diagnostic devices, and software providing decision support. Manufacturers must demonstrate that this software performs reliably and consistently.[50]

The evolving nature of software and software updates present a challenge to both companies and regulators. However, innovation will be supported by maintaining transparency between regulators and developers, and ensuring that developers have a detailed understanding of the regulations and can create a compliant quality plan.

In the US and EU, regulators are in the process of creating regulations that can cope with constantly evolving software. However, their risk-based approaches involve different ideas about what is and what isn't high risk when it comes to AI. The European Commission's (EC's) proposed new AI regulation (for implementation in 2024) suggests that medical devices using AI will fall within its remit. Under the proposal, medical devices and SaMD that use AI would be considered high risk products, making it costly and time-consuming to get such products on to the market.[51] EU guidelines state that trustworthy AI must:

- have human agency and oversight
- be technically robust and safe
- prioritise privacy and data governance
- be transparent
- promote diversity, non-discrimination and fairness, avoiding bias
- benefit societal and environmental wellbeing
- have appropriate accountability mechanisms.[52]

"Evidence generation is not easy, but companies need to tap into the support and advice that is available in the regulatory and health technology assessment world in order to do that."

Life Science Policy and Market Access Expert

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"You have to demonstrate efficiency and better outcomes. Then you have to make it compelling for health authorities and make the business case for change."

Global medical technology company

Furthermore, the ability to explain an algorithm and its appropriate governance are cited as crucial factors for implementing AI ethically.[53]

Whilst the EC is focusing on the risks and building a framework that is risk averse, the US regulator is taking a much more liberal, risk-taking approach. This divergence, together with the regulatory complexity, will deter even more companies from 'being brave' in developing apps and wearables that claim measurable health benefits. Many companies are likely to look at the easier route of AI in self-care and look to launch in the US. Meanwhile the UK government has declared an ambition to create a proportionate light-touch and forward-looking regime to keep pace with the speed of developments in these technologies.[54]

Demonstrating the evidence base post launch for device performance, safety and security

Post launch, diagnostic device manufacturers continue to have a significant burden of evidence generation requirements. In our survey of diagnostics companies, 36 per cent of respondents considered that when attempting to grow and maintain the market for their products, the need to provide post-launch evidence-based assurance about the safety and security of their diagnostic device was a top challenge.

A requirement of the MDR and IVDR, for example, is that throughout the lifetime of a product manufacturers should collate post-market data, systematically gathering clinical data to monitor the safety and efficacy of the product and evaluating performance in line with its intended use.[55] Data that must be recorded (and reported) includes any serious adverse events or undesirable side-effects.

In our July 2022 report *'Intelligent post-launch patient support: Enhancing patient safety with AI'* we discuss how biopharma companies can improve health outcomes by applying AI and advanced analytics to the ever-growing flow of real-world data (RWD) to automate end-to-end pharmacovigilance.[56] Similarly, an AI-supported post-market data system for diagnostics, where data is collected, processed, and used in real time, has the potential to deliver significant efficiency improvements. Devising a scalable and adaptable solution for effectively handling the growing volume and diverse types of incoming data will allow better regulatory compliance by ensuring traceability, and will improve the timeliness and accuracy of submissions.

In addition, companies must gather sufficient evidence to prove the safety and performance of their diagnostic to buyers and end-users. Companies need to provide evidence of improved patient outcomes, in addition to superior performance compared to existing products on the market. Following product launch, manufacturers often conduct larger scale trials to generate performance data using bigger and more diverse patient populations. While critical to device reimbursement and successful adoption, these trials take time and incur significant costs.

Furthermore, new value-based reimbursement pathways place an emphasis on obtaining real world data and evidence (RWD and RWE). This can provide a greater level of insight than traditional randomised control trials. In June 2022, England's HTA institute, NICE, published a RWE framework aiming to improve the quality of data by providing guidance on planning, conducting and reporting RWE studies.[57]

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Improved implementation and standardisation of guidance such as this across Europe would support manufacturers in generating data of a sufficient quality to demonstrate appropriately the safety and performance of their diagnostic tests across geographies. Furthermore, companies should develop strong RWE strategies to mitigate the risks of pitfalls in collecting data in non-controlled settings.[58]

At-home tests, wearables and data security

There are particular concerns around the reliability of at-home tests and wearables, for which results are provided without the oversight of a trained specialist. Crucially, in our survey of diagnostics companies, 40 per cent said that a major challenge to growing the market for a diagnostic device was the willingness of healthcare providers to accept results from wearable and at-home diagnostics. Our interviewees also noted that, although there are many benefits for both patients and healthcare systems, the burden of evidence for home testing is more complex and acceptability is variable between European countries. However, the COVID-19 pandemic has demonstrated the ability of untrained individuals to self-sample and self-test successfully, and for the results to be widely accepted. By generating strong RWE of their diagnostics, companies can demonstrate the usability and clinical applicability of their products more effectively.

"For home testing the burden of evidence is going to be much more complex. It is going to be quite a burden on industry and others."

Industry body

As diagnostics are becoming more connected and generate growing quantities of personal medical data, maintaining the security of data is crucially important. Cybersecurity concerns are pervasive across the MedTech industry and for diagnostics companies the increasing numbers and capability of connected diagnostic devices (as well as imaging machines) create additional risks for data security. The scale of breaches is often far-reaching and the costs can be significant. Consequently, it is imperative that cyber security and data privacy considerations should embedded in diagnostic devices and software from the earliest stages. As recommended in our report '*MedTech and the Internet of Medical Things*', diagnostics companies need to establish a 'security by design' approach and establish real-time monitoring, cyber threat modelling and analysis, and threat mitigation and remediation.[59]

It is also important that healthcare providers, patients and other users should have trust in the security of their data. As increasing quantities of data are captured by advanced diagnostics and shared between diagnostic companies and specialists to improve diagnosis, transparency around this process is vital. An approach to improving transparency in the future could be the use of blockchain – a shared ledger for recording and monitoring data transactions. This technology could support patient data management and transparency.[60]

"It has been and continues to be difficult for non-pharma healthcare interventions to generate evidence of benefit. It's going to be easier for MedTech companies to generate robust evidence now that the regulatory and health technology assessment environment is starting to embrace non-randomised controlled trials evidence - real world evidence - in its assessment."

Life Science Policy and Market Access Expert

New funding models: bringing innovative products to market

"Because of the lack of potential to raise capital here in Europe, many companies go to the US market. One of the top challenges European companies have is in raising cash to build a company even if they have a working product."

IVD company

As healthcare develops new funding, business, and operating models, which focus on improving quality and reducing the costs of providing care (value-based care), diagnostics companies will be required to demonstrate greater evidence about the added value of both their new and enhanced products. Our survey of diagnostics companies found that 29 per cent of respondents were ill-prepared for attracting sufficient funding and investment to develop and launch a new product. Notably, micro and small companies felt least prepared, with 47 per cent of companies with fewer than 50 employees 'not very well' or 'not at all' prepared for obtaining sufficient funding and investment.

While larger multinational corporations (such as global imaging companies) can often rely on income generated from an established portfolio of products to fund the development of new diagnostic technologies, start-ups and small companies rely much more on funds from external sources, such as private equity companies or venture capitalists. This can involve competing for a myriad of funding competitions and grants (such as the Horizon Europe funding programme, which has designated a budget of €95.5 billion towards research and innovation in the EU, spread across a range of work programmes including health, covering diagnostic areas such as decision support tools and chronic disease prediction).[61] [62] Due to the competitive nature of such funding calls, and in many cases a limited scope for eligibility, obtaining funding can be difficult.

A study conducted by Deloitte and MedTech Innovator (MTI) in 2021, which analysed a database of 1,000 MedTech start-ups from 43 countries, found that only one-quarter of companies were supported by government grants.[63]

Instead, start-ups most commonly received funding from the company's founders themselves (68 per cent), angel investors or angel groups (48 per cent), friends and family (46 per cent) and venture capital (37 per cent).[64] Furthermore, around one-third of respondents were supported by an accelerator or incubator programme.

Crucially, companies need to be able to generate sufficient evidence from the initial funding phase to demonstrate the commercial potential of their product to later-stage investors. While our interviewees identified diagnostics and the detection of disease as being a 'hot area' for investment, they noted that providing evidence of improved patient outcomes is required to instil confidence in investors. Strategic partnerships, including merger and acquisition (M&A) deals, licence agreements and co-development can reduce investment risk and provide the money necessary to undertake product development and trials.[65]

An example of an investor partnership is the recently announced Novartis Biome UK Heart Health Catalyst, a partnership between Novartis, Medtronic, RYSE Asset Management and the Chelsea and Westminster Hospital NHS Foundation, which focuses on funding diagnostic ideas in the cardiology space.[66]

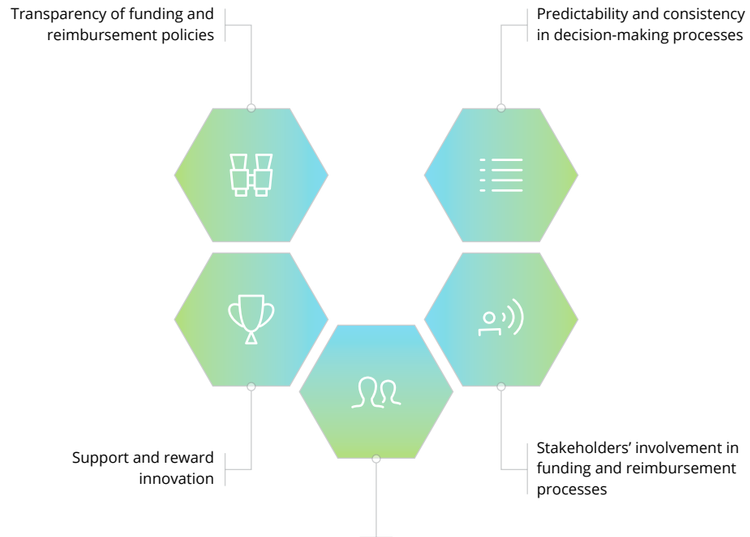
Our interviewees commented that in Europe the approach to investing is generally more risk-averse compared to the US, making it harder for companies to raise funds for innovative products. Europe needs an innovation ecosystem that supports manufacturers to fund the development and launch of their products, in combination with an understanding from innovators about how to demonstrate the value of their technology pre-market.

Device cost and reimbursement

In Europe, medical diagnostics are most frequently purchased by individual healthcare organisations, often funded by a third-party payer organisation.[67] Our interviews with senior stakeholders from across the diagnostics ecosystem emphasised the complexity of the reimbursement processes in Europe. Specifically, each country has its own reimbursement policies and requirements for clinical evidence. This contrasts with the US which is seen as one large consolidated market. Our research found that many companies underestimate the challenge of the European reimbursement structure, and struggle with the length of time between product launch and adoption and the funding of the device at scale, which can be several years.

A fundamental step for diagnostics companies is to develop an in-depth understanding of the differences in Europe, in order to accelerate adoption of their product. MedTech Europe has outlined key principles for funding and reimbursement models (see Figure 6), ultimately supporting health technology assessment (HTA) processes that promote innovation and value-based care.[68] If assessment bodies were to assign diagnostics with value-based codes that demonstrate the value of the product for example, integration into clinical practice could be more readily supported.[69] The incoming new health technology assessment regulation (HTAR) in Europe seeks to 'ensure an efficient use of resources and strengthen the quality of HTA across the Union'.[70] By working closely with opinion leaders and policy makers, companies can adapt to, and help shape, future reimbursement guidelines.

Figure 6. Principles for funding and reimbursement of clinical diagnostics



Source: Adapted from MedTech Europe – https://www.medtecheurope.org/access-to-medical-technology/financing-of-medical-technology/

Real world evidence (RWE) that demonstrates improved patient outcomes is increasingly being sought by purchasers and HTA bodies. The European Health Data and Evidence Network (EHDEN) is developing a platform that provides access to 'findable, accessible, interoperable and reusable' RWE for stakeholders, including health technology assessment agencies.[71] RWE is also central to the strategic plan of UK's HTA body NICE.[72] By continuing to develop an HTA infrastructure that promotes access to diagnostic RWE, diagnostic companies can align themselves better with purchasers' requirements.

Furthermore, there should be clear articulation of the minimum viable product that innovators should create: this can be provided via standardised target product profiles (TPPs) that are agreed by healthcare systems and regulators. TPPs would help innovators to generate evidence that appropriately reflects the safety and clinical performance requirements of the device. Our interviewees identified TPPs as an enabler of rapid innovation during the COVID pandemic, such as rapidly manufactured ventilator systems.[73]

Germany has established an evidence-based reimbursement process – the BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte) fast-track assessment process for Digital Health Applications (DiGA).[74] This process enables new digital products to be assessed rapidly for quality and functionality, and on approval be listed in a directory of solutions that are prescribed to patients and reimbursed by German Statutory Health Insurance. For products with limited RWE, a preliminary one-year listing is possible, giving companies the opportunity to demonstrate the medical benefit of their product within this time, while having access to reimbursement. Adopting new reimbursement models such as this in other areas of diagnostics might be possible for low-risk devices; however for the highest risk devices greater levels of evidence prior to reimbursement will remain appropriate.

Innovation in digital health is particularly susceptible to the development of multiple products for the same application, with large variations in quality and evidence generation. This makes it difficult for healthcare providers and consumers to know which products to reimburse. Case study 2 illustrates how the Organisation for the Review of Health and Care Apps (ORCHA) has developed a trusted digital health quality management platform and digital health assessment process to address this, improving the reimbursement of safe products and increasing transparency around evidence. Overall, closer alignment between European countries is required to standardise evidence requirements for all diagnostics. Our interviewees highlighted the unnecessary burden of having to duplicate clinical studies in different countries to satisfy national requirements.

Case study 2. ORCHA supports health app manufacturers to deliver accredited digital health technologies across health and care systems (England)

Situation
While approximately 350,000 digital health apps are currently on the market, and this number is continually rising, approximately only 20 per cent of these are of sufficient quality to meet safety standards.[75] First conceived in 2012, The Organisation for the Review of Health and Care Apps (ORCHA) aims to support innovators to safely commercialise digital health products, and support health systems to provide widespread access to safe digital health products.

Action
ORCHA has established a robust digital health review process, involving assessing against 350 criteria, including clinical assurance, data privacy and usability.[76] This process incorporates relevant national and international standards and guidelines, and can provide recommendations for areas of unmet compliance with standards such as the UK Digital Technology Assessment Criteria (DTAC) and the Nordic Digital Health Evaluation Criteria (NorDEC).[77] The unique NorDEC programme aims to align digital health standards across Sweden, Denmark, Norway, Finland and Iceland, creating common baseline health assurance criteria.[78]

These assessment processes are part of ORCHA's wider Digital Health Quality Management Platform, containing:

- an end-to-end assessment platform
- health app libraries of compliant apps
- digital health formularies for clinicians
- data insights, including around the adoption and use of digital health products.

Outcome
ORCHA has assessed over 17,000 apps to date.[79] This review and certification process has provided over 3000 clinicians worldwide with the confidence to prescribe health apps directly to their patients via ORCHA's Digital Health Formularies.[80] Furthermore, ORCHA's platform has won multiple awards, and is supporting the safe and successful adoption of digital health products.[81] [82]

Among the clinicians who responded to our survey, 60 per cent highlighted the cost associated with adopting new technologies as their top challenge. Despite having a generally positive view of the potential for technologies to improve patient outcomes, a fifth expected new technologies to have a negative impact on efforts to reduce healthcare-related costs.

Value-based procurement, pricing policies and alternative funding models

Value-based procurement is becoming more common, whereby products are reimbursed at a rate proportionate to value. A 2020 survey of medical technology companies conducted by MedTech Europe found that value-based procurement was an important driver of success for nearly 80 per cent of the survey respondents.[83] Diagnostics companies that develop robust health economic models could improve their probability of success by demonstrating the long-term cost-benefits associated with adoption of their technology. Typically, these models demonstrate the performance metrics of the diagnostic (such as sensitivity, specificity, and overall quality and validity), in addition to providing a detailed analysis of how using the product will save money over a period of time (including both direct and indirect savings due to more efficient diagnosis).

Increased access to RWE in Europe (supported by the proposed European Health Data Space) is expected to support price negotiations for relevant products.[84] As rates of inflation in Europe reach record levels, maintaining an effective pricing strategy will be increasingly important.[85]

These and other alternative funding models could accelerate the adoption of innovative diagnostics. For example, the UK government's Tackling Antimicrobial Resistance five-year action plan includes a commitment to developing alternative funding models for faster diagnostics that support targeted treatment and streamlining the regulation process.[86] Innovative funding models for diagnostics, such as the subscription-based model for antimicrobials, could help to incentivise innovation.[87] Moreover, both the private sector and direct-to-consumer (DTC) markets have developed alterative reimbursement paths for some diagnostics. The shift in location of diagnostic services from hospitals and centralised laboratories to local hubs, in conjunction with the rise in patient empowerment, has raised the profile of these alternative pathways.[88]

"A health economic model is core…You must show you have the sensitivity and specificity and where money can be saved."

IVD Company

Reforming diagnostics | Turning challenges into enablers

Supply chains: reducing the impact of disruptions

Most supply chains globally have been disrupted by a variety of factors: the COVID-19 pandemic and its aftermath; extreme weather events; geopolitical turbulence and in particular the war in Ukraine; and for the UK, Brexit. Diagnostics have been affected by the disruptions in several ways, for example in shortages in the supplies of laboratory testing equipment, personal protective equipment and electronic components (notably semiconductors). Shortages have also been caused by a surge in demand for diagnostics products (from blood pressure cuffs to CT and MRI scanners), and the demand for semiconductor chips is expected to double between 2021 and 2028 as healthcare systems tackle patient backlogs.[89] [90] This industry-wide shortage poses an acute threat to the supply of diagnostic devices.[91] Furthermore, the limited availability of iodinated contrast media for CT scans has recently resulted in urgent changes to the operation of radiology departments to maintain patient care.[92]

Supply chain issues affect both the development and supply of medical products and IVDs. Furthermore, if manufacturers are forced to swap to alternative components, there can be significant financial and regulatory implications associated with demonstrating their equivalence. This can even affect simple swaps, such as the use of alternate brands of plasticware in the laboratory when previously validated consumables are temporarily unavailable.

Given the problems and risks, our interviewees from diagnostics companies told us that they had developed strategies to safeguard their supply chains. These include adopting greater levels of planning and forecasting, such as increasing inventory levels and obtaining access to multiple sources of supply for materials and components, even though this can be expensive and complex from a regulatory point of view. It is now important to build flexibility into the design of diagnostics wherever possible, for example by gaining approval for a suite of alternative components for a product where the future supply of existing components may be at risk. Our interviewees noted that the current CE marking system has greater flexibility than in other countries in terms of using similar components via the significant change assessment process, and they expressed a wish that this process would be replicated in the new UK regulations.

In addition to the above actions to manage supply risk, other solutions include enhancing end-to-end visibility through digitalisation (including more accurate demand prediction and increased data sharing and transparency), boosting supply chain agility (through stress testing business continuity plans and building redundancy into operations) and utilising broker relationships. These have been highlighted as crucial areas for businesses to build supply chain resilience.[93] [94]

Traceability and the need for a unique device identifier

The traceability of medical devices and the ability to share product data are essential elements of the new European regulation. A requirement of the MDR and IVDR is for a Unique Device Identifier (UDI) to be placed on all products to support greater traceability.[95] This measure is similarly being adopted by the UK, with MHRA announcing in July 2022 plans to authorise the use of GS1 standards for this purpose.[96] These standards, already adopted by over 90 per cent of medical device manufacturers in the US, are open technology-independent standards that 'enable healthcare partners to have automatic and efficient access to product data location information and transactional messages'.[97] [98] The standards for identification provide traceability throughout the supply chain from manufacturer to distributor to consumer using globally unique numbers, with standardised barcodes for data capture and access, and interoperable standards for product data exchange.[99] By implementing such standards, product recall and inventory management operations are streamlined.

Environmental, social and governance commitments

Another important consideration for diagnostics manufacturers is the increasing focus on environmental, social and governance (ESG) measures and the need for a circular economy for the supply and manufacture of their products. In England, the NHS has pledged to become the first net zero healthcare system, setting a target of 2040 for emissions that it controls directly and 2045 for the emissions that the NHS can influence. Its July 2022 publication '*Delivering a 'Net Zero' National Health Service*' outlines ambitious plans for achieving these targets, including mandating that all suppliers must also meet their commitment to net zero emissions.[100] This ambition will drive transformation in the design, manufacture and distribution of many diagnostic products, with the NHS planning to 'substitute low-carbon alternatives where possible'.[101] Areas for change include shifting from single-use to reusable items and the design of durable (and repairable) products.[102]

For 85 per cent of our survey respondents ESG considerations are 'somewhat' or 'to a great extent' incorporated into the lifecycle of their products. This is encouraging progress, but the importance of ESG will only continue to rise as more healthcare systems across Europe expect more sustainable practices in their suppliers. Among our survey respondents 21 per cent indicated that the financial costs of implementing changes are currently the main factor restricting their organisation in being more ambitious in meeting ESG targets. This adds to the existing financial pressures associated with developing and launching a new product, and greater support is likely to be needed from governments and healthcare systems to enable companies of all sizes to transition successfully to net zero. To prepare for future challenges, diagnostics companies should consider adopting a 'Sustainability by Design' mindset in their approach to product development.

Workforce and skills: technology-enabled capacity building

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

Wearables and AI company

Whereas diagnostics companies responding to our survey frequently cited 'healthcare culture and attitudes' as a key barrier to the successful adoption of their new products, our survey of clinicians highlighted the lack of workforce training and skills around new technologies as a barrier to adoption. In our 2020 report '*Digital transformation: Shaping the future of European healthcare*' we identified the need for automation and digitalisation to help alleviate workforce shortages and emphasised that innovative products should be easy to use, meet an identified need and help improve workforce productivity and/or patient access. The report also identified a need to provide clinicians with training in digital health, genomics, and AI.[103] While healthcare providers are responsible for the development and training of their workforce, diagnostics companies also have a role in ensuring they are adequately supporting the end users of their technology via appropriate learning materials, on-demand support and on-site training.

A 2021 study of healthcare practitioners (HCPs) found that among European clinicians the most trusted sources for learning about new medical device technologies and procedures are medical congresses and meetings. The next-most trusted is receiving information from peers and sales representatives.[104] Furthermore, the most valuable sources for learning about innovation in medical device technologies are online videos and courses, due to the ability to access information 'on demand' (which was considered important for 94 per cent of European respondents). A priority focus area for diagnostics companies should therefore be to develop accessible materials that are easily available to device users, in conjunction with physical promotion of their products. Case study 3 illustrates how the medical device company TympaHealth developed its own in-house training programme to address this issue.[105]

Case study 3. TympaHealth: delivering hearing assessments within the community via portable diagnostic technology

Situation

Approximately one in six adults in Europe suffer from hearing loss, at an estimated annual cost of up to €581 billion.[106] Furthermore, hearing loss has been associated with an increased risk of falls, isolation, and dementia.[107] [108] Despite becoming an increasing disease burden, waiting times to receive hearing care are rising significantly. Improving access to hearing care with innovative technology, award winning TympaHealth Technologies has developed a portable device that combines a digital otoscope, microsuction wax removal and a hearing screener.

Action

TympaHealth is currently working with a range of partners to deliver ear and hearing care within the community, including GPs, private healthcare providers, care homes and pharmacies.[109] The platform utilises the imaging capabilities and Tympa's in-built connectivity to enable this convenient hearing assessment within 30 minutes. This is the world's first all-in-one ear and hearing health assessment system and integrates digitally to support data sharing and remote care.[110] The device aims to improve access to audiological care by designing the device for non-specialists to use in any location, with the additional support of telehealth systems.

An important aspect of TympaHealth 's offering is the in-depth training provided to all customers via their dedicated 'TympaHealth Training Academy'.[111] Held regularly at locations across the UK, these courses enable trainees to practice using the device with bespoke 'Simulation Heads'. Face-to-face professionals can give immediate feedback, supporting clinicians from a range of background to use the device. In addition, webinars and online learning provide further support. This training is accredited by the British Society of Audiology, ENT UK, and the British Society of Hearing Aid Audiologists (BSHAA). In addition to reforming the clinical pathway for audiology, their research institute is contributing to hearing health knowledge.

Outcome

Since launching in 2021, over 150,000 individuals had been assessed using TympaHealth's system by February 2022.[112] Supporting its growth across a global market, TympaHealth recently secured $8 million of investment to continue to expand the 'democratisation of ear and hearing care'.[113]

European healthcare systems: serious workforce shortages

Not only is there is a shortage of skills and training to support the adoption of new diagnostic technologies, but across Europe healthcare systems are experiencing significant staff shortages due to chronic under-investment and demand pressures (including those relating to COVID-19).[114] The European Labour Authority's 2021 annual report on labour shortages and surpluses in Europe found that nursing professionals are the occupation with the most severe shortages.[115] Generalist medical practitioners, health care assistants, home-based personal care workers and nursing associate professionals were also among the occupations with the biggest labour shortages.

These shortages threaten the ability to deliver diagnostic services safely, both in hospitals, communities and people's homes. However, one way of tackling these shortages is to use technology to improve service capacity – digitalisation, automation and the development of new diagnostic technologies that improve efficiency and reduce downstream healthcare system costs and improve patient outcomes (see our report on *Digital Transformation: Shaping the future of European healthcare*).[116]

"Automation is not going to be a nice to have, but a must have."

Global medical technology company

Workforce shortages in radiology and pathology

Clinical radiologists and interventional radiologists are the lynchpin for diagnosis and treatment of cancer, stroke and heart disease where accurate and timely diagnosis is critical to outcomes. Diagnostic and interventional radiologists have also been at the forefront of the fight against COVID-19. Likewise, laboratory staff and pathologists have been central to the efficient handling of tests. However, there is a global shortage of radiologists and pathologists.[117]

In the UK, the Royal College of Radiologists 2021 census shows a worrying situation of staff shortages. For example there is a 29 per cent shortfall in consultant radiologists (1,669 Whole Time Equivalents) and 98 per cent of clinical directors said they were worried about workforce morale, stress and burnout in their departments, which has a negative impact on workforce retention and patient safety, including backlogs and delays.[118] Similarly in 2018, the pathology workforce census found that only three per cent of histopathology departments had enough staff to meet clinical demand, yet histopathology requests to laboratories had increased on average by around 4.5 per cent annually since 2007. The 2022 census, due to be published in the autumn, is likely to show a worsening situation.[119]

Our interviewees highlighted radiology and pathology services as areas 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 substantially. For example, the accelerated adoption of automated on-demand molecular testing was driven by the COVID-19 pandemic: advanced equipment performing repetitive manual sample processing steps reduced test turn-around-times, increased throughput, and improved quality.[120] In addition to the automation of diagnostic equipment, the digitalisation of records is streamlining data collection and improving the traceability of testing and supporting regulatory oversight.[121]

Many applications of AI in clinical practice so far have focused on the diagnostic imaging sector. The benefits of these solutions are wide-ranging, from reducing image acquisition and reconstruction times, to reducing image noise, to automating stroke assessment and predicting Alzheimer's progression.[122] [123] [124] Increasingly however, laboratory services are embracing automation to improve productivity, including the use of AI to improve the accuracy of testing (see Case study 4).

Case study 4. How AI is transforming pathology services in Europe

The demand for pathology laboratory services is increasing by approximately 4.5 per cent each year, with pathologists facing increased workloads and complexity of work as new developments in testing and analysis emerge.[125] Despite this, many labs are facing significant and growing staff shortages. Across Europe there are approximately 23,000 pathologists, however there are regional disparities. [126] [127] While the UK has over 40 pathologists per million population, countries such as France and Germany have between 20-29 per million, and Poland has less than 20. Globally, the disparities are even greater.

AI-enabled technologies have the potential to help address workforce shortages by enhancing existing laboratory systems and processes and extrapolating additional information from samples to provide more efficient and accurate diagnosis. A 2022 survey of experts from computational pathology, academia and industry indicated that the most promising application of AI is for the prediction of treatment response directly from routine pathology slides.[128] However, there are numerous and wide-ranging applications of AI in pathology, including cell detection and mutation prediction. Incorporating AI into pathology could also provide new knowledge of disease mechanisms and ultimately lead to enhanced diagnosis.

The widespread use of AI would bring new ways of working, with the roles and responsibilities of pathologists evolving, complemented by technology that improves diagnostic quality.[129] In September 2021 Paige Prostate gained the first ever FDA approval for an AI-based diagnostic software in pathology, supporting improved accuracy, reproducibility and efficiency of cancer detection in prostate biopsies.[130]In a landmark clinical study the technology resulted in a 70 per cent reduction in false negative cancer diagnoses, and a 24 per cent reduction in false positive diagnoses.[131] In May 2022, Paige received CE-IVD and UKCA marks for the Paige Prostate Biomarker Suite AI software, paving the way for further AI-based pathology innovation in Europe.[132] Bigpicture, a partnership funded by the EU Innovative Medicines Initiative established in 2021, aims to create the first European ethical and regulatory compliant digital repository containing three million pathology images to support the development of new AI solutions in Europe.[133]

AI algorithms are being used to process data from across the diagnostics spectrum, including pathology tissue analysis and analysis of genomic data.[134] [135] Many other innovations are emerging through partnership working. While these developments and initiatives have enormous potential to help healthcare providers address some of the workforce problems, especially in supporting them with more efficient and accurate diagnoses, advances also need to reflect the changing regulatory landscape and address ethical issues.

Conclusion

Early and more accurate diagnosis saves lives. 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 realising the future of health. By prioritising actions to address the current challenges we believe that diagnostics companies will be crucial drivers of predictive, preventative, personalised and participatory (4P) care.

In our report *The future of diagnostics: technology-driven personalised and preventative healthcare in Europe* we explore the evolving role of diagnostics in shaping new clinical pathways and consider how the adoption of disruptive diagnostic technologies can help healthcare systems transition from volume-based to value-based care, and deliver a future in which diagnostics are crucial drivers of more predictive, preventative personalised, participatory (4P) care. The report also identifies six overarching challenges that need to be overcome and a series of actions that the various stakeholders should consider taking today to realise the future of diagnostics.

In this companion report, we have taken a deeper look into each of these six challenges and explored potential solutions. All the solutions involve some form of automation and digitalisation of diagnostic systems and processes, with an important role for AI-enabled technologies to improve the speed and accuracy of diagnostics. Moreover, diagnostics companies will be able to use the vast amounts of data they generate to help patients improve their well-being, anticipate health issues, and help change the day-to-day behaviours that affect their health.

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