HealthcareTransformers

Roche

6 diagnostic trends shaping *the future of healthcare*

Insights for healthcare executives

What we aim to **answer**

What impact will digital technologies have on in vitro diagnostics in the future?

What benefits will increased use of digital tools bring to healthcare professionals, labs, healthcare systems and patients?

What are the potential pitfalls of the increased use of digital technology?

Contents

The value
of in vitro diagnostics

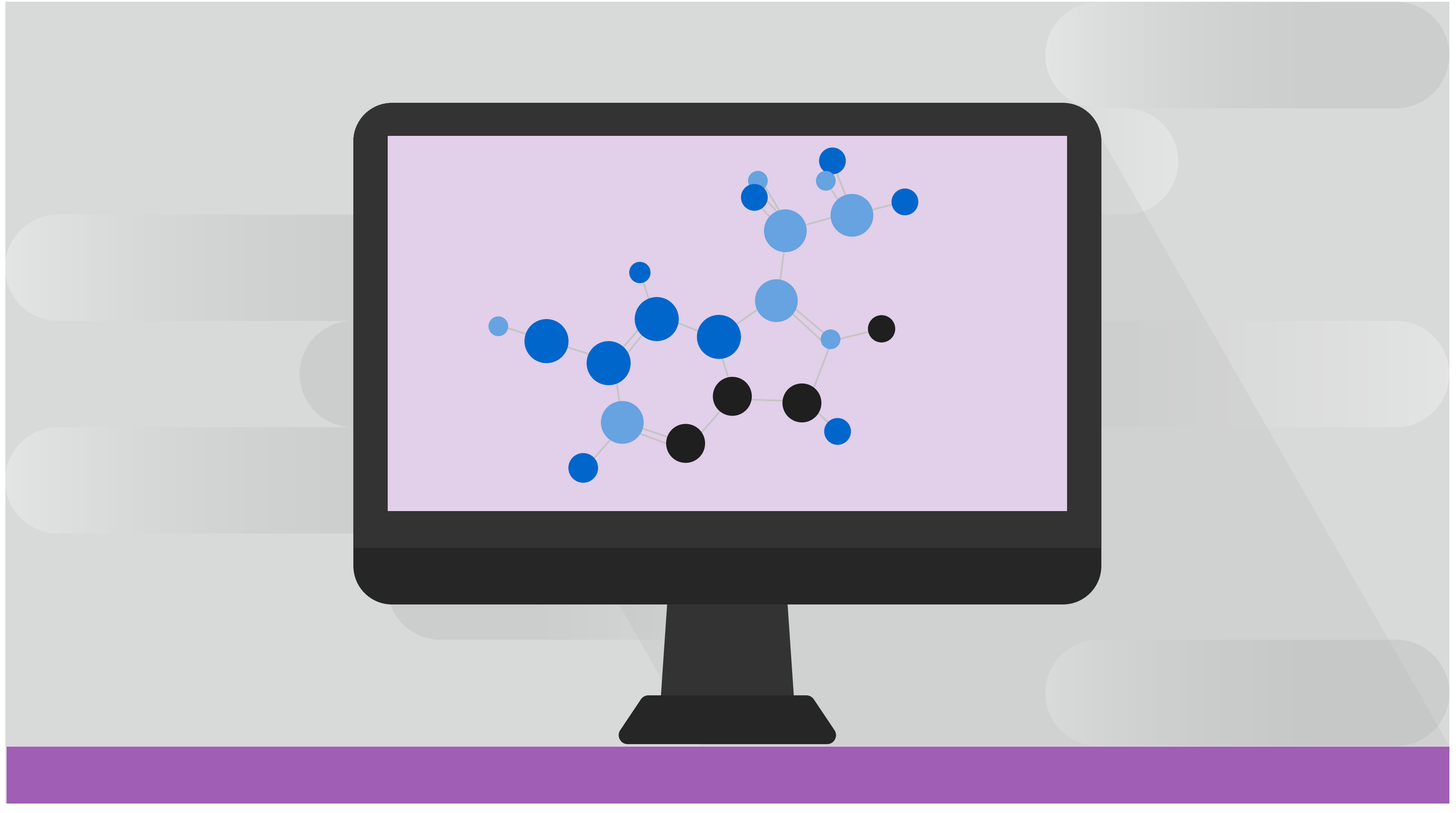
In vitro diagnostics (IVDs) play a key role in today's healthcare system.

Within samples such as blood, saliva, and tissue, significant information about the state of a person's health can be found that can be used to help diagnose, treat, monitor, or even cure disease. For instance, IVDs can help determine if certain types of cancer are present, if someone may be having a heart attack, or if a person is infected with a virus such as human immunodeficiency virus (HIV). On top of the medical value, in vitro diagnostics may also provide significant economic benefits, influencing over 66% of clinical decision-making, while accounting for only about 2% of total healthcare spending.[1]

SOME OF THE VARIOUS TYPES OF IVDS AVAILABLE TODAY INCLUDE:

CLINICAL CHEMISTRY DIAGNOSTICS

Clinical chemistry applies chemical, physical and biological methods, generally to body fluids such as blood or urine, to assist clinicians and practitioners in the prevention, diagnosis and treatment of diseases.[2]



MOLECULAR DIAGNOSTICS

Analyzing biological markers in an individual's genetic code and how their cells express their genes as proteins. The technique is used to diagnose and monitor disease, detect risk, and decide which therapies will work best for individual patients.[3,4]

TISSUE DIAGNOSTICS

Removing and staining tissue for testing, especially in oncology.[5]

IVD testing covers a massive spectrum of conditions. In fact, there are over 40,000 different IVD products available that provide information to doctors and patients.[1] These tests have become such a fundamental aspect of modern medicine that the World Health Organization has designated 122 test categories as essential for “advancing universal health coverage, addressing health emergencies and promoting healthier populations”.[6]

The current limitations *of diagnostic tests*

DIAGNOSTIC TESTING, HOWEVER, HAS ITS LIMITATIONS. THREE OF THE MOST IMPORTANT ARE:

THE "SNAPSHOT EFFECT"

Samples used for diagnostic testing, especially blood or tissue, are taken at a certain moment that is essentially frozen in time. Therefore, the results reflect the health condition at that specific point in time only.

SILOED DATA

This reflects the disjointed nature of the diagnostic testing landscape. Diagnostic tests are conducted in a myriad of locations: in large central labs, in hospital emergency rooms, on a handheld machine in a doctor's office, or even at a patient's home. All too often, the data from each is evaluated and used in isolation to address a specific need only. This diminishes its value because it becomes extremely difficult to compile it into a comprehensive mosaic across the health system as a whole.

THE RISING COMPLEXITY

The sheer number of tests available make it difficult for healthcare professionals (HCPs) to select which tests to carry out, and in what sequence. There are over 40,000 different IVD products available, and this vast array of tests provide results on a huge range of conditions.[1]

The number of tests that exist today continue to grow exponentially, and HCPs are struggling to cope with the wealth of data that they produce. One observational study calculated that the average general practitioner spent 1.5 to 2 hours per day reviewing test results,[7] adding to an already stressful work environment.

Ironically, the proliferation of testing options leads to an interesting paradox of both over and underuse of diagnostic tests. Doctors overuse certain tests, that is, order a test when guidelines do not recommend it (for example, imaging for low back pain); and, at the same time, they do not order other tests when guidelines do recommend them (for example, spirometry to confirm or refute a diagnosis of chronic obstructive pulmonary disease, which can potentially delay diagnosis and treatment.[8]

> *Overall, these limitations mean that diagnostic tests today generally aren't able to provide a view of the broader picture of a person's health. It's like trying to piece together the story of your adventure vacation from a few snapshots, we inevitably miss critical parts of the overall story.*

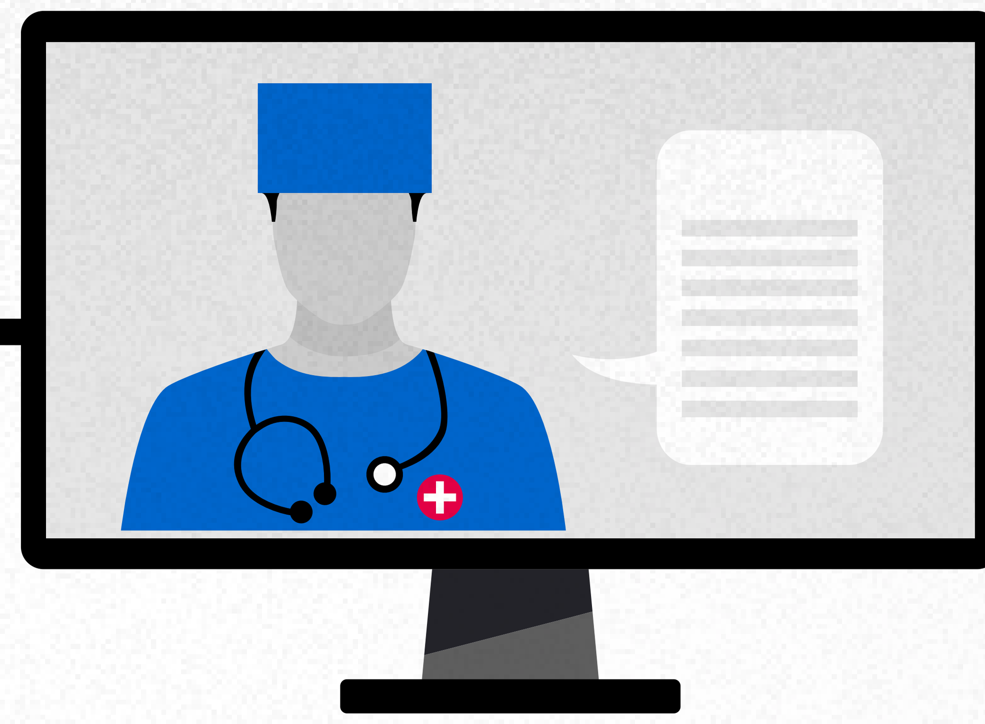
The digital and data-driven *future of diagnostics*

For many of the most common conditions today, these limitations are hindering the ability of healthcare professionals to accurately and adequately leverage diagnostics to provide care for their patients. Are patients developing cancerous tumors that are too small to see? Is that tremor suggestive of the onset of a neurodegenerative disease? Do they have organ-damaging high blood pressure, but feel no symptoms?

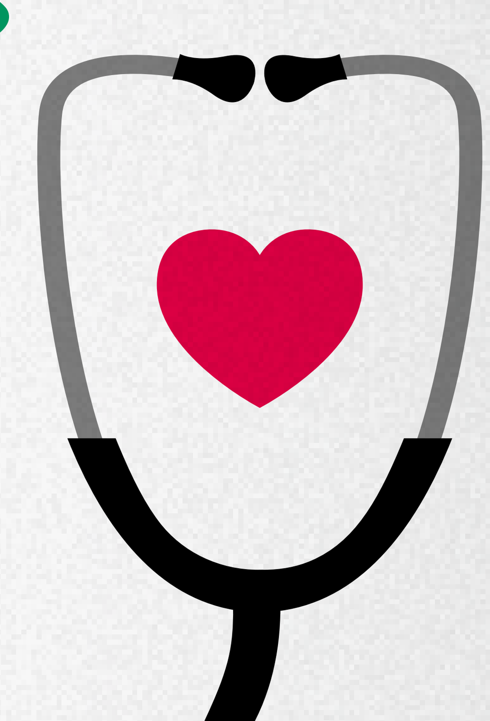
The next step would be to move diagnostics from one-off measurements to nearly continuous health monitoring. The resulting data might help healthcare professionals and their patients better understand, in real time, if there is a problem that can be addressed or treated.

Today's overstressed health systems are plagued by delays in obtaining timely results from traditional diagnostic labs, often caused by laboratory turnaround times.[9] With testing often done in central labs, HCPs and patients rely on samples reaching laboratories safely and reports being returned in a timely manner to avoid diagnostic delays.

Digital diagnostics could help relieve some of the capacity and resource pressures on the health system and improve the speed and efficiency of the process.



Far from being distant, this future is already emerging today, thanks to breakthroughs in digital technologies. The marriage of digital technology and diagnostic tests is setting the stage for advancing and improving patient experience and outcomes, while at the same time improving testing efficiency.
This could help drive cost savings across the healthcare system.

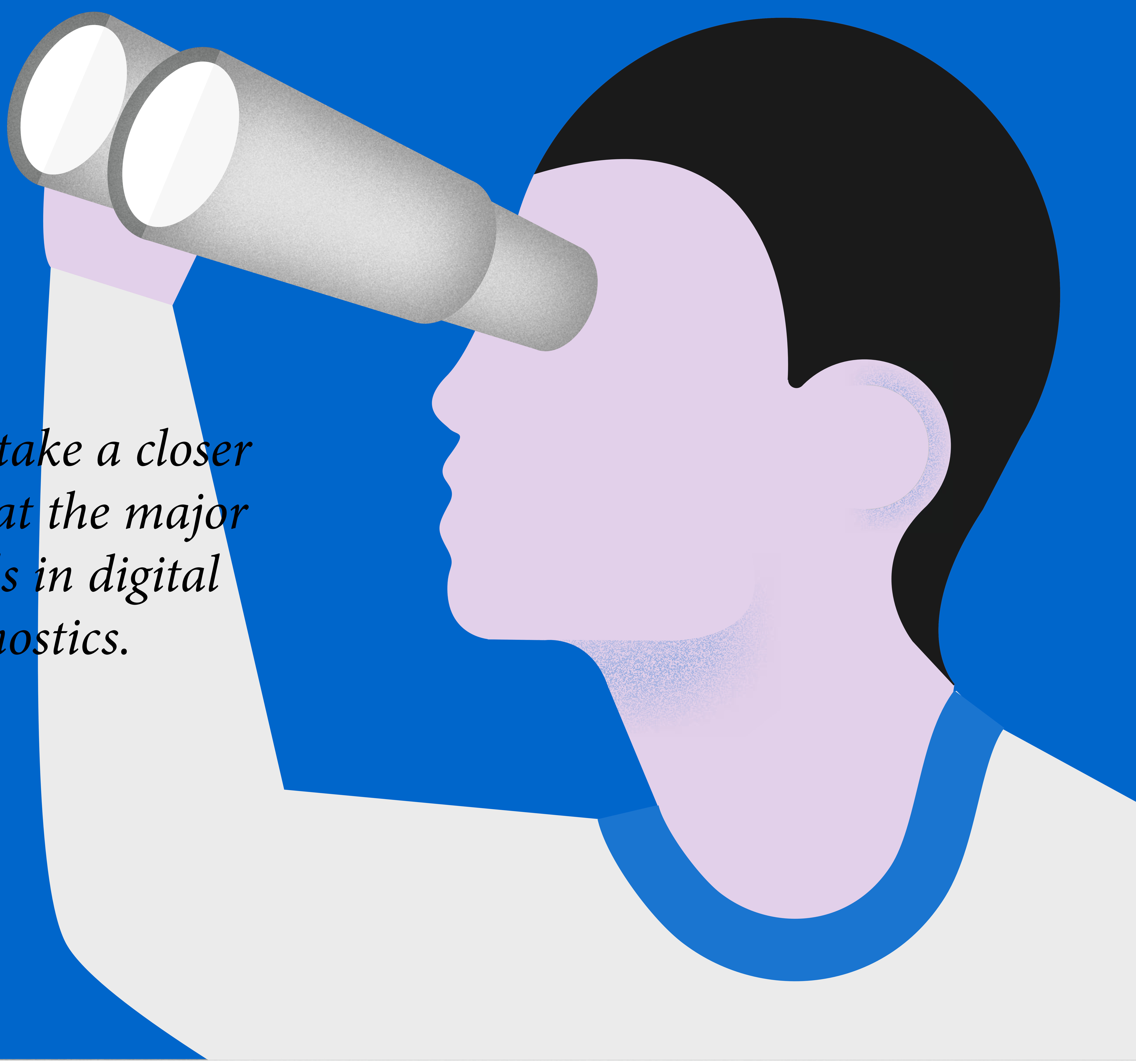


ESSENTIALLY ALL STAKEHOLDERS STAND TO BENEFIT AS DIAGNOSTICS GO DIGITAL, INCLUDING:

- **LABS:** Create better outcomes and lower their costs
- **PHYSICIANS:** Make faster and more data-driven clinical decisions, not just interpret results
- **PAYERS:** Help manage patient populations or healthy individuals to contain costs
- **PATIENTS:** Engage more in their own health and benefit from improved outcomes

6 diagnostic trends

transforming healthcare



Let's take a closer look at the major trends in digital diagnostics.

I. Point of care testing and emerging at-home diagnostic solutions

Consumers are increasingly open to new channels of care, particularly at home. Now, innovative new technology is allowing patients to take their healthcare into their own hands.

Point-of-care testing (POCT) provides patient testing outside of the central laboratory in order to make critical lab tests more quickly accessible to patients and help drive treatment in a more timely manner. Rather than test being run via a large central lab, the test and, critically, the results, are conducted in locations closer to where patients tend to be: the operating theater, critical care unit, maternity unit, emergency department, nursing homes, physician's office, on emergency vehicles like ambulances, at the local pharmacy or at home for example.[10]

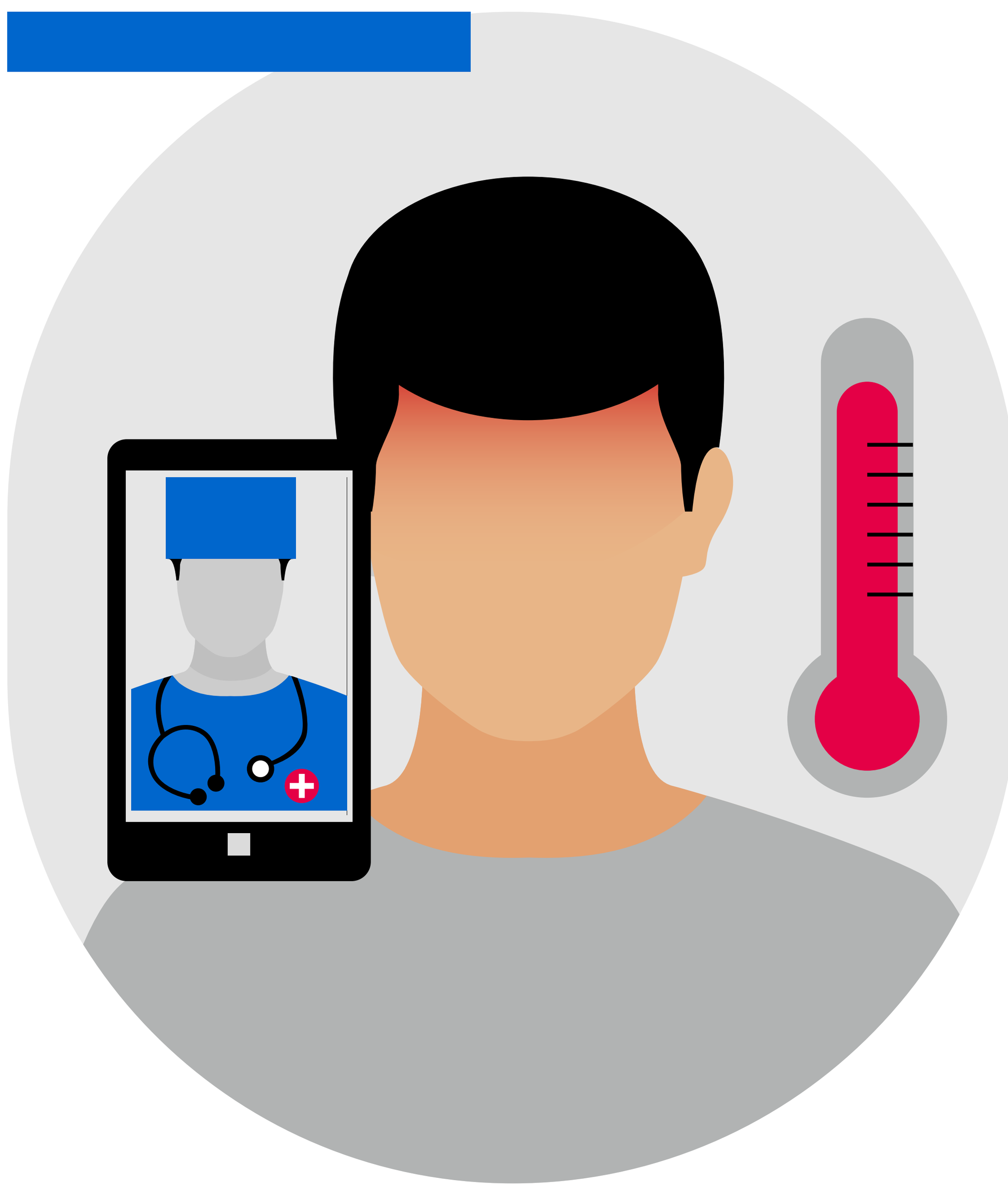
POCT is essential for the rapid testing near the patient, which facilitates better disease diagnosis, monitoring, and management.

At-home medical testing especially has evolved considerably over the past few decades. The first "at home" test that was widely used were over-the-counter pregnancy tests[11], but now there are at-home tests available for a range of conditions: urinary tract infections, sexually transmitted diseases, strep infections, insulin levels, stomach ulcers, genetic tests and even cancer.[11,12]

It can also reduce the time to results, as travel time for samples and results are reduced or eliminated. Altogether, POCT can potentially enable quicker medical decisions, which may help to improve health outcomes for patients.[13]

EXAMPLES ILLUSTRATING THE ADVANCEMENTS IN POCT

INFLUENZA



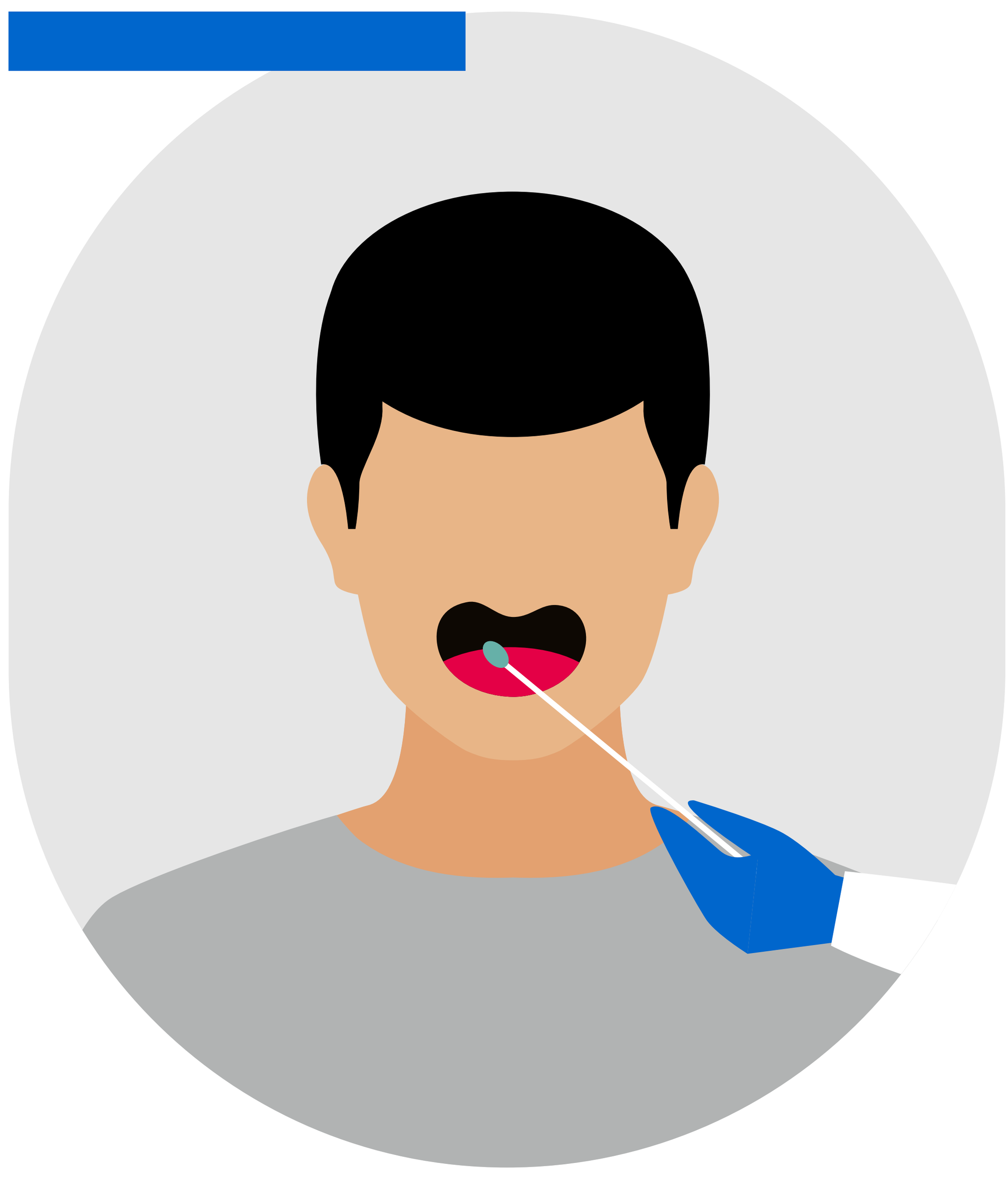
Various types of at-home influenza tests are being developed, using nucleic acid amplification, similar to tests done in clinical or public health labs.[14] The testing kit would then send information to a physician via a connection to the patient's smart phone through an app or the device itself. The physician could then prescribe a treatment, if needed, that can be delivered to the patient's door. The biggest benefit is that patients would not have to leave their homes, which could help reduce the spread of the illness.[14]

HEART HEALTH

Other digital solutions aim to improve the management or "care pathway" of diseases. One example is the digital disease management platform by Veta Health, which improves the ambulatory care experience for chronically-ill patients. Through the Startup Creasphere, Veta Health and the Netherlands Heart Network (NHN) started the "Care4Hearts" project in collaboration with Roche. By capturing the care journey of heart failure patients outside of clinical settings with Veta Health's solution, this pilot project showed improved adherence for patients to their management plan and increased patient satisfaction.[15]

The Cleveland Clinic, a leading cardiac center in the US, is leveraging Bluetooth technology to link pacemakers directly with a patient's smartphone, which can then send data to their doctor. Doing so eliminates the need for any additional bedside equipment.[16]

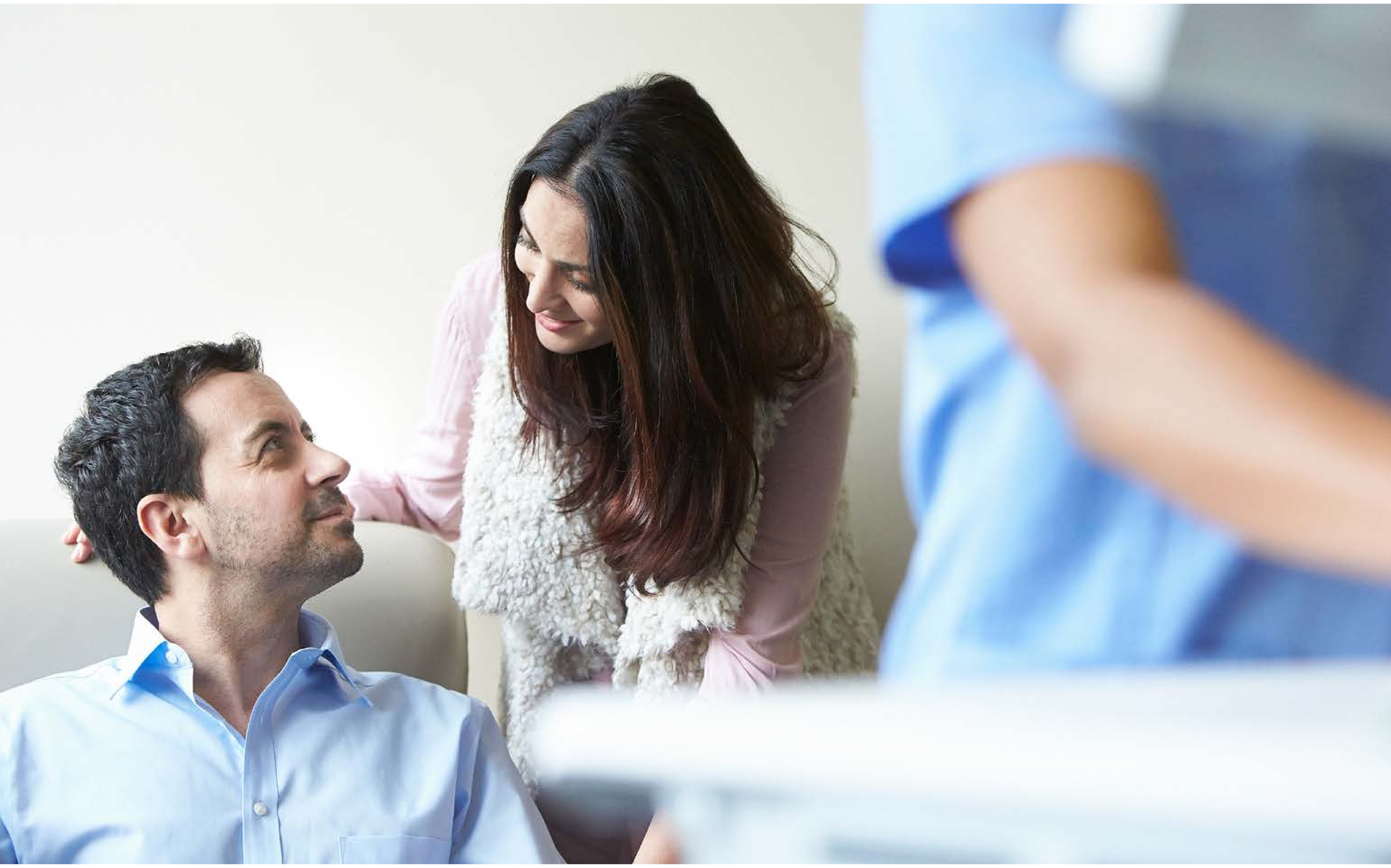
BLOOD AND SALIVA SAMPLING



New technological breakthroughs are poised to disrupt the status quo even further. For example, researchers in Sweden are investigating a paper diagnostic, a device that is printed on a credit-card-sized piece of card stock that can analyze blood and saliva samples. It is simple to use: you switch it on by pressing a button, then apply your sample to a circle and simply wait for a digital reading, which is then sent to a mobile phone. In theory, it can be used to let patients monitor the state of their own diabetes, heart disease or other chronic diseases.[17,18]

NEW GENERATION OF WEARABLES

A group of Chinese researchers is also developing what may become the next generation of wearable device, a kind of e-skin that uses flexible electronics and nanotechnology embedded in an ultrathin film. This film is only a few atoms thick, so it can press close to the skin, making it comfortable and sensitive; despite its thinness, however, it contains sensors to track and broadcast data such as blood pressure and pulse in real time. [17,19]



BENEFITS

- Fast and simple specimen handling with little or no transportation required
- Rapid testing near the patient facilitates better disease diagnosis, monitoring, and management in several common conditions
- Helps keep patients out of hospitals or physician's offices and in the comforts of home
- Enables quicker medical decisions
- Generates extensive real-world data that can be used for additional scientific advances

CHALLENGES & REQUIREMENTS

- Reliability of POC tests may not always be on par with central labs
- Patients and physicians may not necessarily be experts in running tests
- Patients may be less comfortable collecting some of the biological samples required
- Data is not useful until and unless it is interpreted
- Uncertainty around data security and legal implications of collecting large amounts of data via POC tools

II. Predictive and personal genetics

> *As the name suggests, predictive genetic tests use a blood, hair, skin or other tissue sample from a person to predict future risk of disease.*[20]

The potential is enormous, as these tests can identify mutations that increase a person's risk of developing genetic disorders before any symptoms appear.[21] This early identification provides the opportunity for targeted interventions that screen, carefully watch or even actively attempt to prevent morbidity and mortality.[20]

The paradox, of course, is that a predictive genetic test informs about a future condition that may (or may not) develop. There is no sure way to determine if a specific condition will develop, when it may appear and how severe it might be. Beyond this uncertainty, there is also a risk that any treatments or interventions taken on the basis of the results are by nature based on their possible benefit, however, evidence supporting the benefit may be lacking.[22,23]

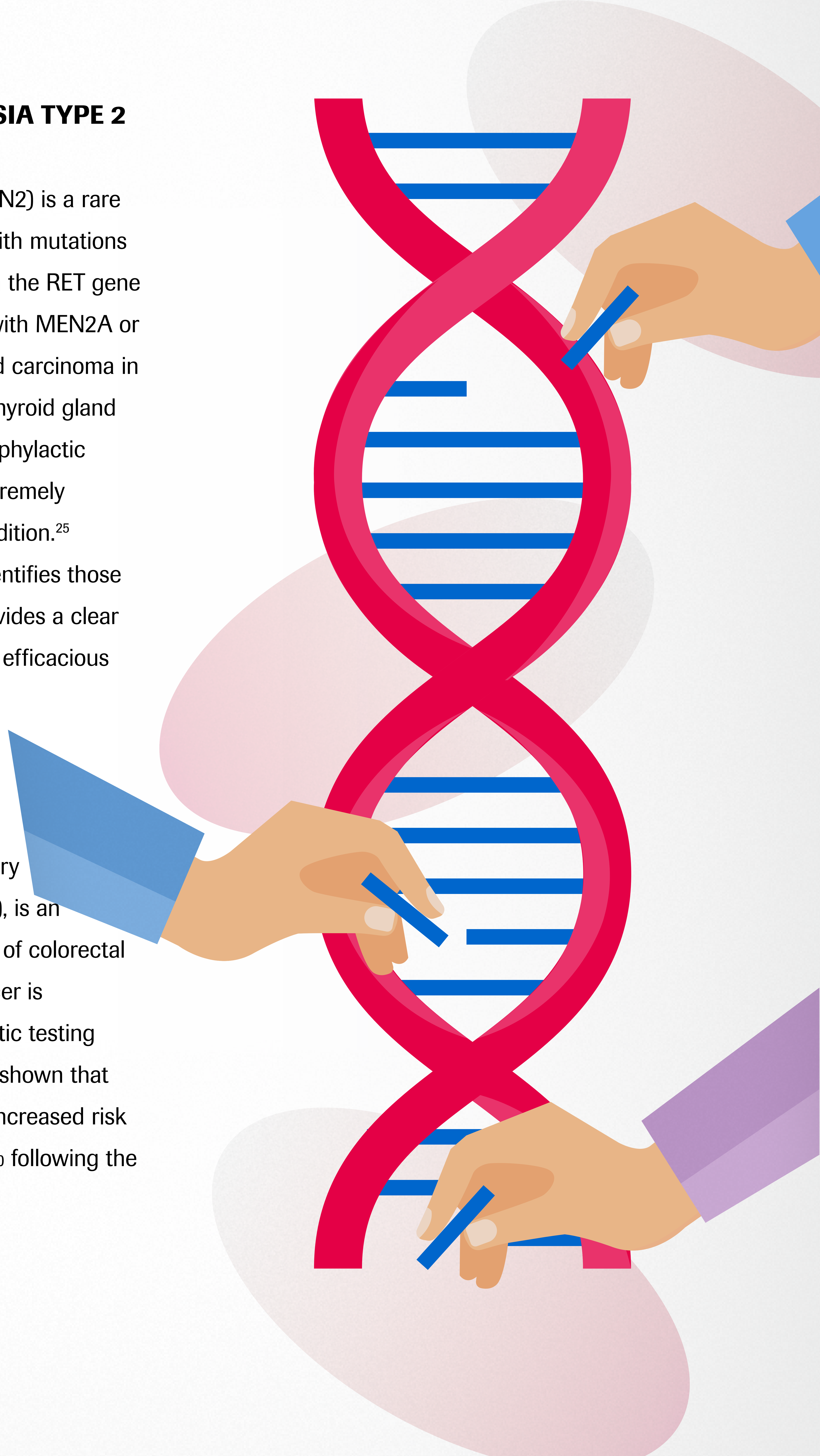
HOWEVER, PREDICTIVE GENETIC TESTS COULD HAVE SUBSTANTIAL BENEFITS TO THE HEALTH OUTCOMES OF PATIENTS AS ILLUSTRATED BY THE FOLLOWING CONDITIONS:

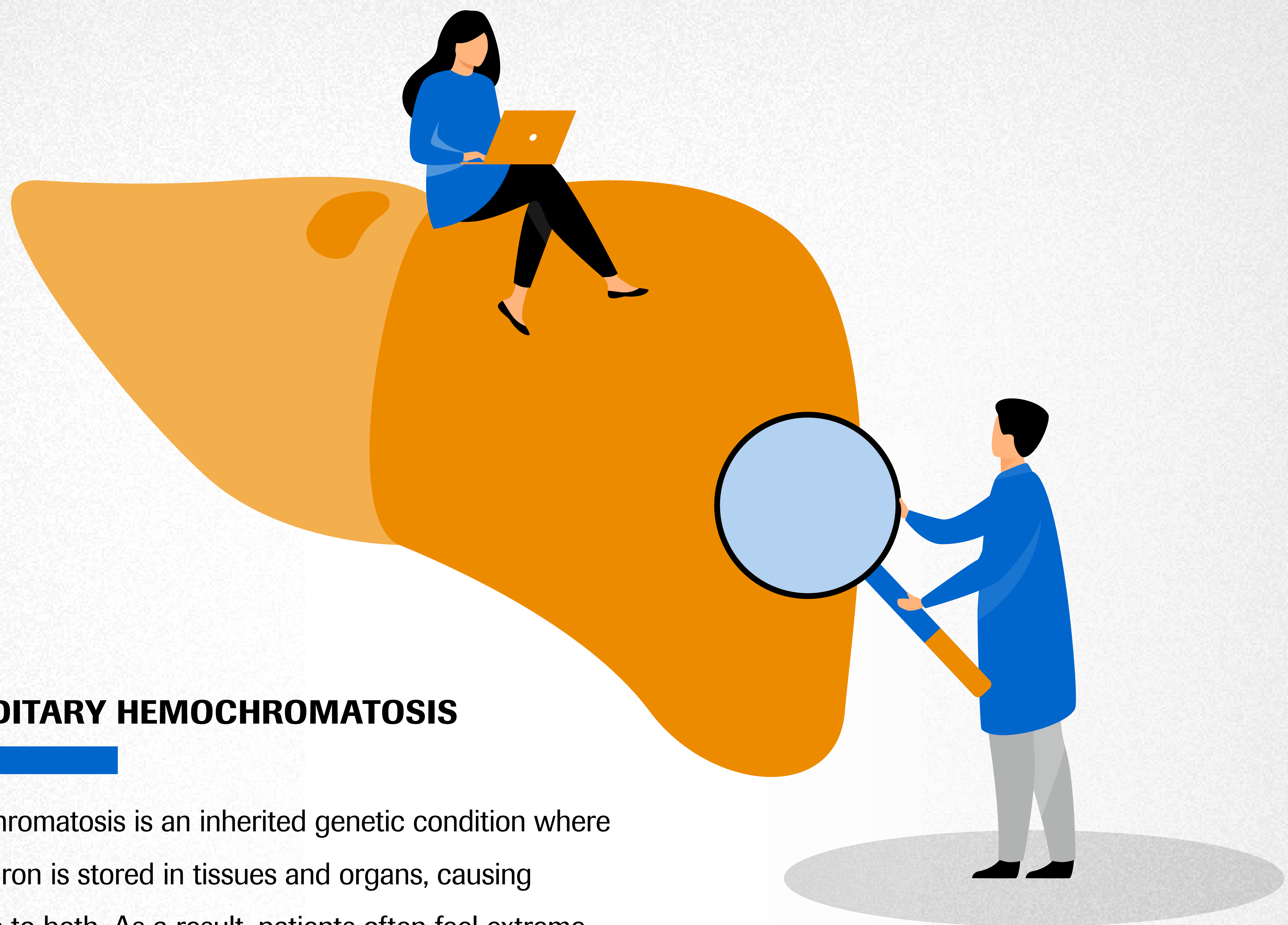
MULTIPLE ENDOCRINE NEOPLASIA TYPE 2

Multiple endocrine neoplasia type 2 (MEN2) is a rare hereditary condition that is associated with mutations in the RET proto-oncogene. Mutations in the RET gene are found in more than 95% of families with MEN2A or MEN2B, and the risk of medullary thyroid carcinoma in these people is nearly 100% unless the thyroid gland is proactively removed.[24] Fortunately, prophylactic thyroidectomy has been shown to be extremely effective in successfully treating the condition.[25] Predictive genetic testing in this case identifies those who will benefit from surgery. It also provides a clear path to prevent the disease thanks to an efficacious early intervention.

COLORECTAL CANCER

Lynch syndrome, also known as hereditary nonpolyposis colorectal cancer (HNPCC), is an inherited disorder that increases the risk of colorectal cancer.[26] About 5-10% of colorectal cancer is hereditary.[20] In this case, predictive genetic testing is an extremely useful tool. Studies have shown that colorectal cancer screening in those at increased risk decreases overall mortality by about 63% following the removal of polyps.[27]





HEREDITARY HEMOCHROMATOSIS

Hemochromatosis is an inherited genetic condition where excess iron is stored in tissues and organs, causing damage to both. As a result, patients often feel extreme fatigue, joint pain, abdominal pain, and weight loss, with an eventual progression to diabetes, arthritis and liver disease.[28] Presymptomatic testing of individuals with high levels of iron in their blood can test for mutations in the HFE gene to help determine if their condition is caused by hereditary hemochromatosis. All first-degree relatives of anyone diagnosed with hemochromatosis could also undergo genetic testing to determine if they are at risk for developing the condition.[29,30] The results of predictive and presymptomatic testing can help drive treatment, such as regular blood removal, which can help reduce symptoms and prevent serious complications from developing.[30]

> *Predictive genetic testing has great potential for accurate risk assessment for many genetic conditions.*

However, there are risks. Because a test done today is negative, it does not mean a person may not develop a condition later. Likewise, a positive result does not mean that a person is guaranteed to develop the condition, and therefore any preventive treatments may be useless, or even harmful.[20]

On an ethical note, once a genetic test is done, the results may shed light on other areas (paternity, risks for other family members) that were unintended.[31]

The utility of testing depends on the level of risk and, perhaps equally importantly, how accurately that risk can be calculated. It also depends on the preventive and/or treatment options available.[20] When the factors align, for example when the risk is high, the predictability is high, and the solutions proven effective, predictive genetics becomes an extremely useful and even lifesaving tool.

BENEFITS

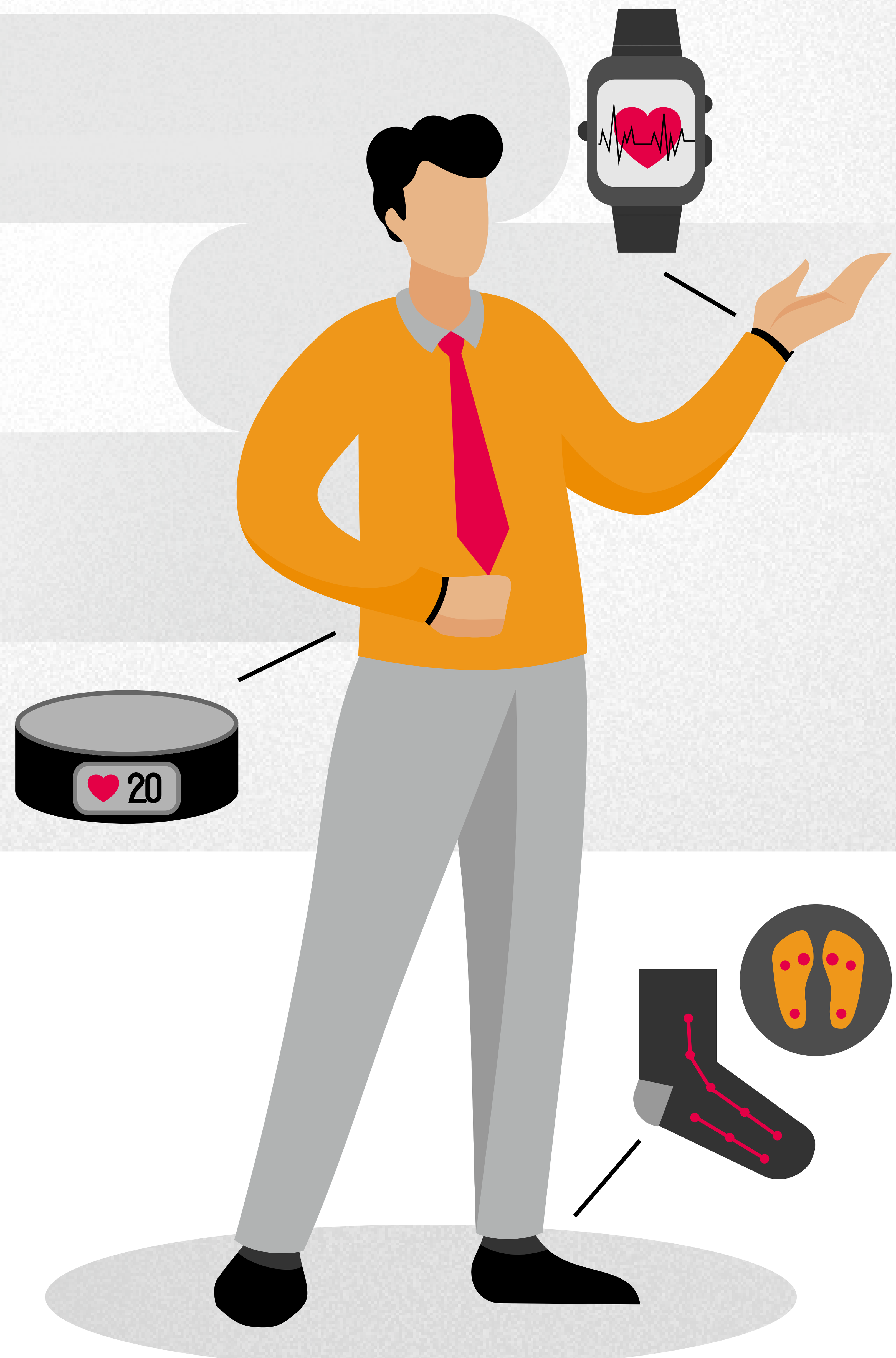
- Early identification of at-risk individuals could lead to better screening, surveillance, and prevention
- Reduced hospitalizations and costly treatments later if conditions prevented or treated early

CHALLENGES & REQUIREMENTS

- Future condition may or may not develop
- Even if it does, unclear when it may appear and how severe it will be
- Utility of testing varies widely

III. Real-time diagnostics

Real-time diagnostics specifically address the "snapshot"-type testing, which may provide only a partial picture of a patient's health.

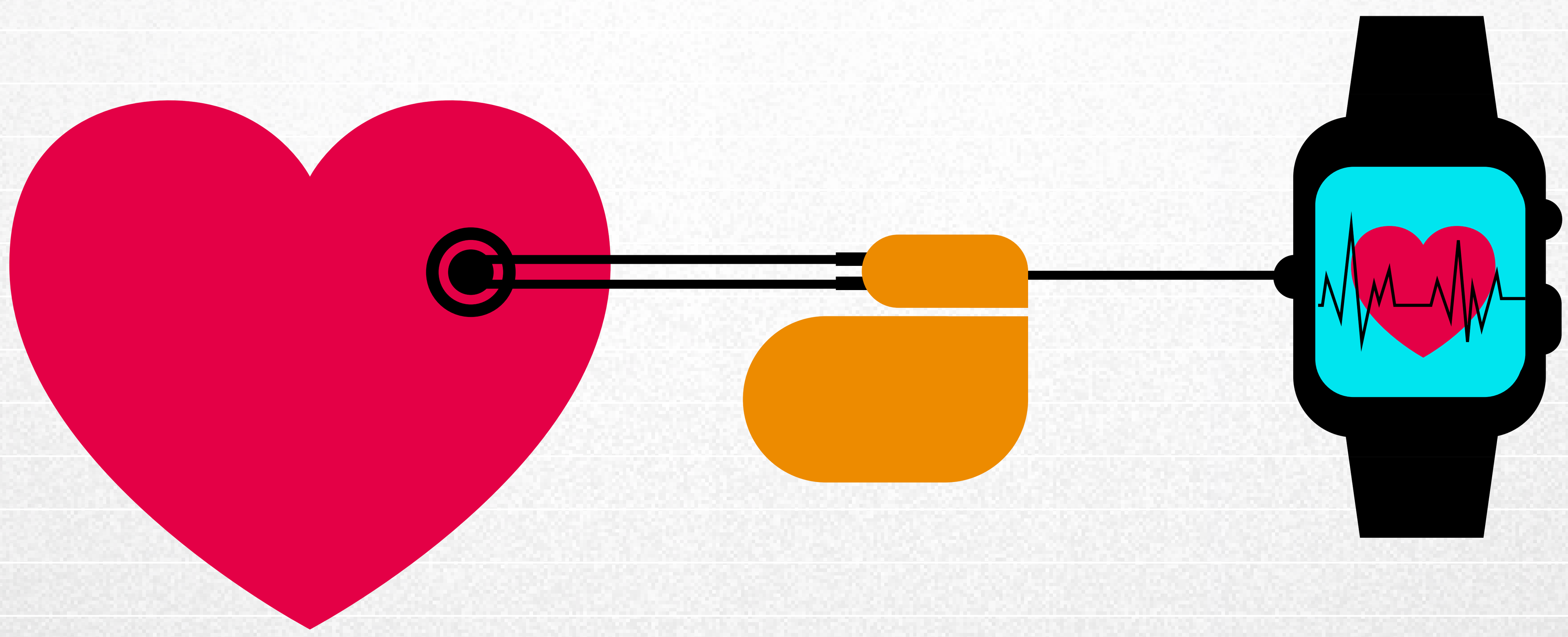


Now that wearable devices are becoming widespread and common, gathering real-time data from patients is now a possibility. This is even more the case as wearables evolve from traditional devices to something more akin to accessories. They may be watches, clothing, bandages, glasses, contact lenses and rings, all of which are conveniently attached to a person's body.[32] But the possibilities go even further: implantable and ingestible devices, or built into or connected with items that we all use regularly each day, like the toilet.[33]

These and other groundbreaking technology that is still being developed provide a ready-made platform to monitor patients' health status on a continuous basis.[32]

Wearable biosensors can collect physical health information such as heart rate, blood pressure, skin temperature, respiratory rate and body motion. They can be used to track a person's general health and well-being, with algorithms watching passively for changes that might be worth further testing or monitoring.[34]

Some examples of real-time diagnostics, both today and in the future:



WEARABLES IN CLINICAL CARE SETTINGS

Wearable, real-time diagnostics, however, aren't limited to the home; they could also have a major impact on how in-hospital care is delivered. For example, they could help to triage patients in the emergency room based on vital signs gathered from wearable monitors. Intensive care units are investigating them to tailor alarm systems to help notify staff of patients in distress based on heart rate, arrhythmia and sleep patterns. Wearables could also improve monitoring of non-bed ridden patients in clinical and hospital settings. The wireless connectivity allows freedom from bulky wires and machines, improving patient comfort and mobility.[34]

WEARABLES AS ELECTROCARDIOGRAMS

Some smart watches, worn by millions of people worldwide each day, already include a built-in electrocardiogram (ECG) sensor, that can alert the wearer to irregular heart rhythms.[35] Similarly, there are also ultra-small portable cardiac monitoring devices and software that can continuously record and transmit ECG data to a smart phone and from there to a hospital center or directly to the doctor. This data can be used to provide physicians with heart rate patterns to better diagnose and monitor symptoms of conditions such as arrhythmia or atrial fibrillation.[36,37]

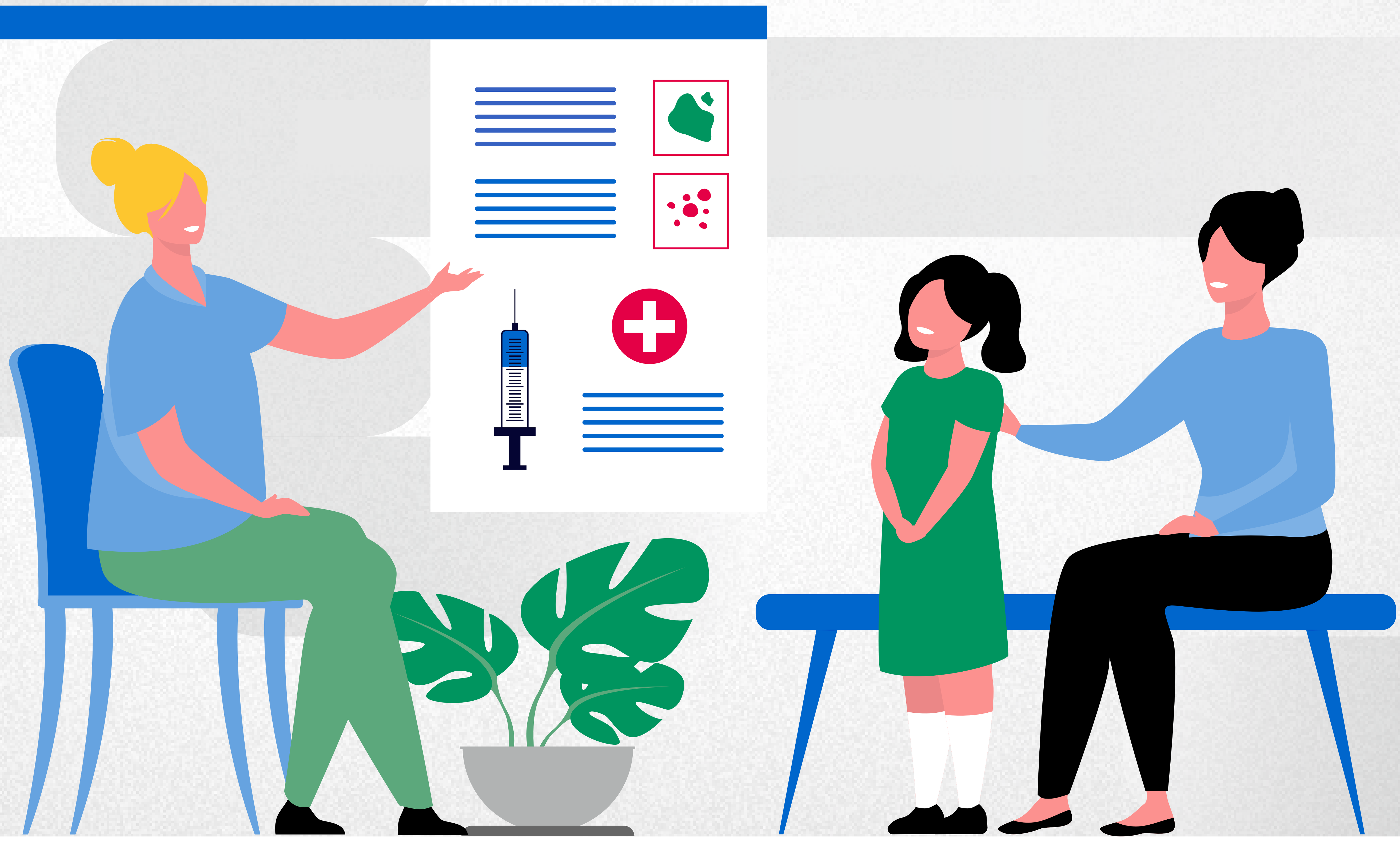
BENEFITS

- Convenient and easy-to-use devices, often connected to existing wearables
- Enables patients to be monitored continuously
- Provides instant feedback on any problems at any time
- Creates a much bigger and more robust data set for treatment decision-making

CHALLENGES & REQUIREMENTS

- Data generated can be overwhelming
- Requires processes and tools to help manage next steps

IV. Clinical decision support solutions



Today, most diagnostic tests deliver numbers and are generally very accurate and successful in doing so.

But, what the healthcare professional (HCP) is trying to determine when they conduct a diagnostic test is what to do next with their patient. Lab results may provide a set of numbers, but the HCP must then work out the context to use that number and decide how to treat the patient. The amount of information needed to make the correct treatment decisions has become so overwhelming that the average clinician is unable to effectively and reliably integrate it into their decision-making.

Enter clinical decision support (CDS) tools. CDSs are technology tools that help filter the enormous amounts of data and suggest next steps for treatments for a particular patient in a particular situation. They provide doctors, administrative staff, patients, caregivers, with information that is filtered or targeted to a specific person or situation. They can also highlight information that a physician may not have seen, or flag potential problems, such as dangerous medication interactions.[38]

CDS TOOLS ARE ALREADY MAKING A DIFFERENCE IN SEVERAL AREAS OF HEALTHCARE SYSTEMS TODAY – FROM PREVENTION TO DRUG-DRUG INTERACTIONS TO ELIMINATING UNNECESSARY TESTS. SOME EXAMPLES INCLUDE:

VENOUS THROMBOEMBOLISM

In one study, CDS systems that alerted physicians to the need for venous thromboembolism prophylaxis were successful, reducing the rates of symptomatic and asymptomatic deep-vein thrombosis and pulmonary embolism by 41%.[39]

DRUG-DRUG INTERACTIONS

Adverse reactions caused by drug-drug interactions are a major cause of hospitalizations each year, especially in older patients.[40] Harding University and Unity Health-White County Medical Center found that combining a CDS system with genetic testing data could reduce hospital readmissions for home health patients using multiple medications by 52%, and reduce emergency visits by 42%.[40] In addition, the study showed that, for older patients at high risk of adverse drug events, drug-drug and drug-gene interaction testing reduced the risk of death by 85% while creating cost savings of over $4,300 USD per person.[40]

COMPUTED TOMOGRAPHY (CT) SCANS

Similarly, a study was conducted to evaluate an electronic tool that helps clinicians determine the need for CT imaging for minor head injuries. Using the Concussion or Brain Bleed app, developed at Yale and the Mayo Clinic, plus integrated bedside clinical decision support and a patient-centered educational component, they were able to reduce the delivery and costs of unnecessary CT scans for minor head injuries.[41]

SEPSIS

Algorithms can also aid in clinical decision-making. One collaboration between Roche and GE Healthcare aims to identify patients before they go into sepsis, attempting to prevent this deadly condition. Using conversational artificial intelligence, the product will guide healthcare professionals to patients that start to develop patterns that may become septic. To do this, the software pulls together in vivo and in vitro information, combining data from a patient's hospital monitoring equipment with their biomarker, genomic and sequencing data, helping physicians to identify, or even predict sepsis before it sets in.[42]

The opportunity for clinical decision support systems is to transform diagnostic test results from mere numbers into much more practical advice such as, "this is a heart attack" or "this is sepsis". This gives the healthcare provider much more relevant and practical information that they can use to take informed actions to improve patient outcomes.

BENEFITS

- Provides healthcare providers with more relevant data than just “numbers”
- Helps sort through mountains of data to find relevant information for treatment
- Creates a “per patient” tailored treatment
- Reports generated could be shared with patients to create more meaningful and transparent results
- More efficient use of laboratory testing, reducing costs and hospital resources
- Early and accurate diagnosis leads to better patient outcomes, helping save costs to the healthcare system

CHALLENGES & REQUIREMENTS

- Requires significant investment in algorithms, connectivity and cloud computing to host, and a CDS platform to run
- Real world data is needed to train and develop robust algorithms
- Algorithms are not all equally reliable in their ability to predict next steps

V. Data-driven lab optimization solutions

Let's look at the Oxford University Hospitals Microbiology lab as an example. This lab processes more than 600,000 unique samples a year.[43] Blood culture represents a small percentage of these samples. However, each blood culture might produce tens or even hundreds of data points and generate data of varying format (images, spectra, categorical, and numerical). Now imagine multiplying this by thousands of tests per day, each day, over years.[44]

Large-scale clinical laboratories like Oxford face an efficiency challenge. Labs are constantly seeking ways to reduce the number of unnecessary tests in ways that increase the value of their offerings.
At the same time, the sheer volume of tests they do run each year generates a vast amount of data. The question is how best to capture and extract information from that dataset to help improve their operations.

Laboratories may only make up a small proportion of overall healthcare spend, but there is still pressure on doctors to order fewer tests and ask labs to do more work for less money. The days of fee-for-service- and transaction-based models are coming to an end. Today, labs are being reimbursed based on the quality and value of the services they can provide, and this trend is gaining traction.[45] The move away from fee-for-service payments is a means to examine ways to streamline lab operations and reduce unnecessary testing. Any extent to which laboratories can avoid unnecessary testing represents a contribution to the financial bottom line.

HERE ARE SOME AREAS OF FOCUS TO HELP BOOST EFFICIENCY WITH DATA-DRIVEN SOLUTIONS:

IT SYSTEMS

A business intelligence and analytics system provides a means of extracting large amounts of data from the existing laboratory information system, and then the ability to analyze that data to answer questions. In the past, processing so much information manually might have taken days or weeks, but newer analytics systems that leverage big data can accomplish the same task in seconds.[45]

> *An analytics system provides the data needed to identify sources of unnecessary testing so that laboratory managers can improve test utilization.*[45]

One such analytics system is Viewics, from Roche. Viewics is a software tool that complements lab and hospital testing solutions that integrates data efficiently from a broad array of IT systems in the laboratory and other healthcare settings. The goal of the system is to help lab and hospital decision-makers make more effective and fact-based decisions to reduce waste and improve the clinical effectiveness, as well as the operational and financial processes, of their institutions.[46]

CLINICAL DECISION SUPPORT TOOLS

Clinical decision support tools can also be used to drive laboratory testing efficiency. A system used in a Veterans Affairs hospital geared towards overseeing laboratory utilization reduced the number of unnecessary tests by over 11% without compromising patient care. In addition, it delivered a cost savings averaging more than $150,000 USD per year for the two years of the study program.[47]

LAB STAFF

Improved and efficient instruments are not the only requirement to run a more efficient lab. In fact, the lab staff themselves are critical to improving operating efficiency. A recent survey of lab managers showed that 52% ranked developing staff as one their top goals[48], with 41% stating that current workflow requires optimization, citing improving productivity and throughput as a strategic change required to achieve this.[48]

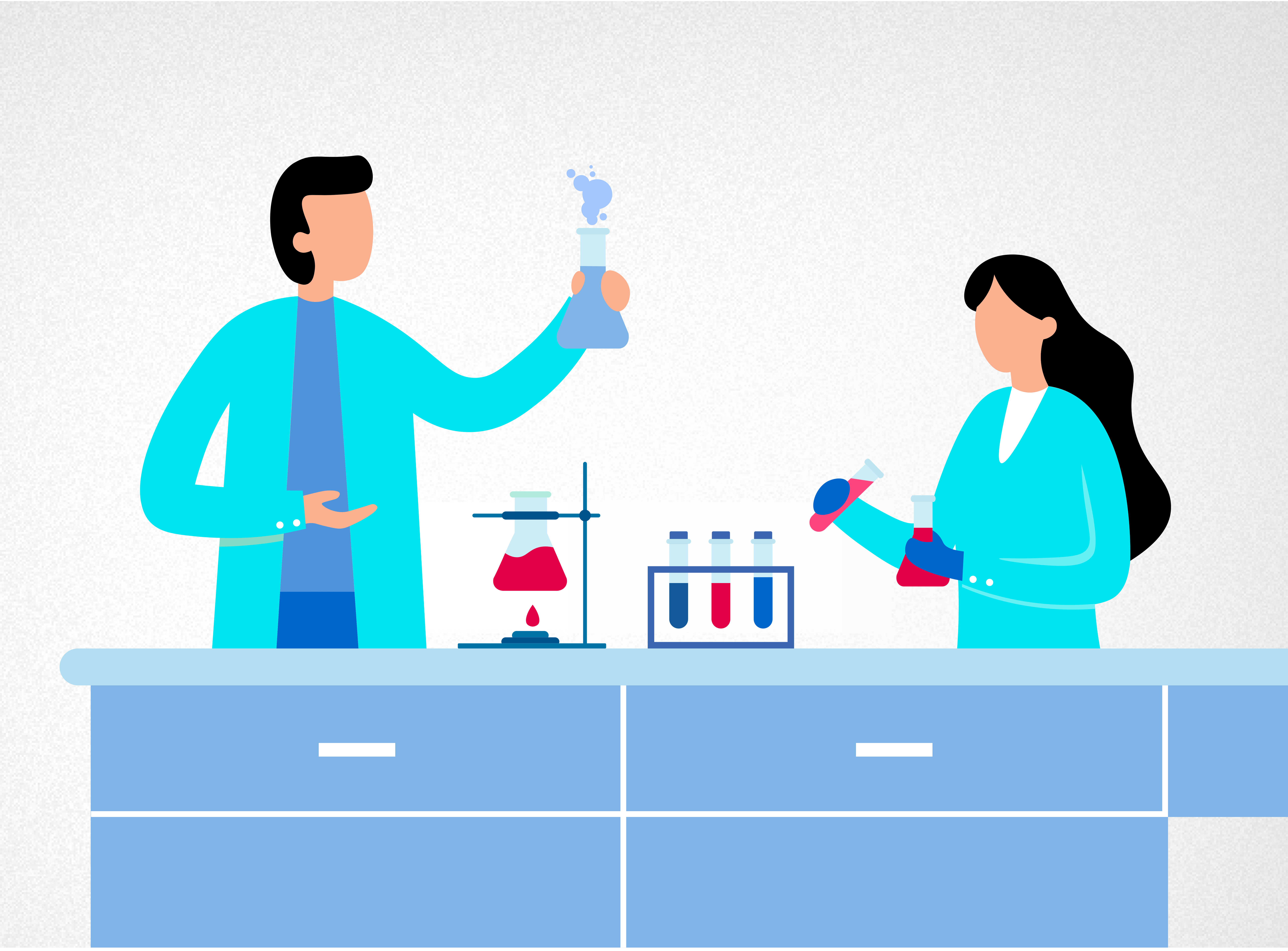
However, labs are facing a staffing crunch. While test volume continues to rise, it is becoming harder and harder to find qualified laboratory techs needed. In the US alone, there were 18,000 clinical laboratory science (CLS) program vacancies in 2018, but only 5,000 graduates from accredited CLS programs each year.[49] Similar challenges are faced in the UK, where staffing challenges have caused burn out, low morale, high sickness absences, increased error rate, poor team spirit, diminished productivity and suboptimal laboratory service delivery.[50]

INVENTORY AUTOMATION

Digital tools can help overcome this, helping the lab staff to focus on higher value tasks while boosting morale, reducing turnover and streamlining processes, including automated sample verification, quality control and calibration; real-time inventory management; remote system support to catch maintenance issues before they become problems.

A case study in Germany showed that implementing digital solutions to address these kinds of issues resulted in a 77% reduction in time to conduct inventory and place orders, a 35% percent reduction in time to manage and process inventory and an 89% reduction in inventory checks.[49]

This helps to reduce errors, improve morale, and boost the efficiency of the lab, all while ensuring that employees are engaged, developed and motivated to succeed.

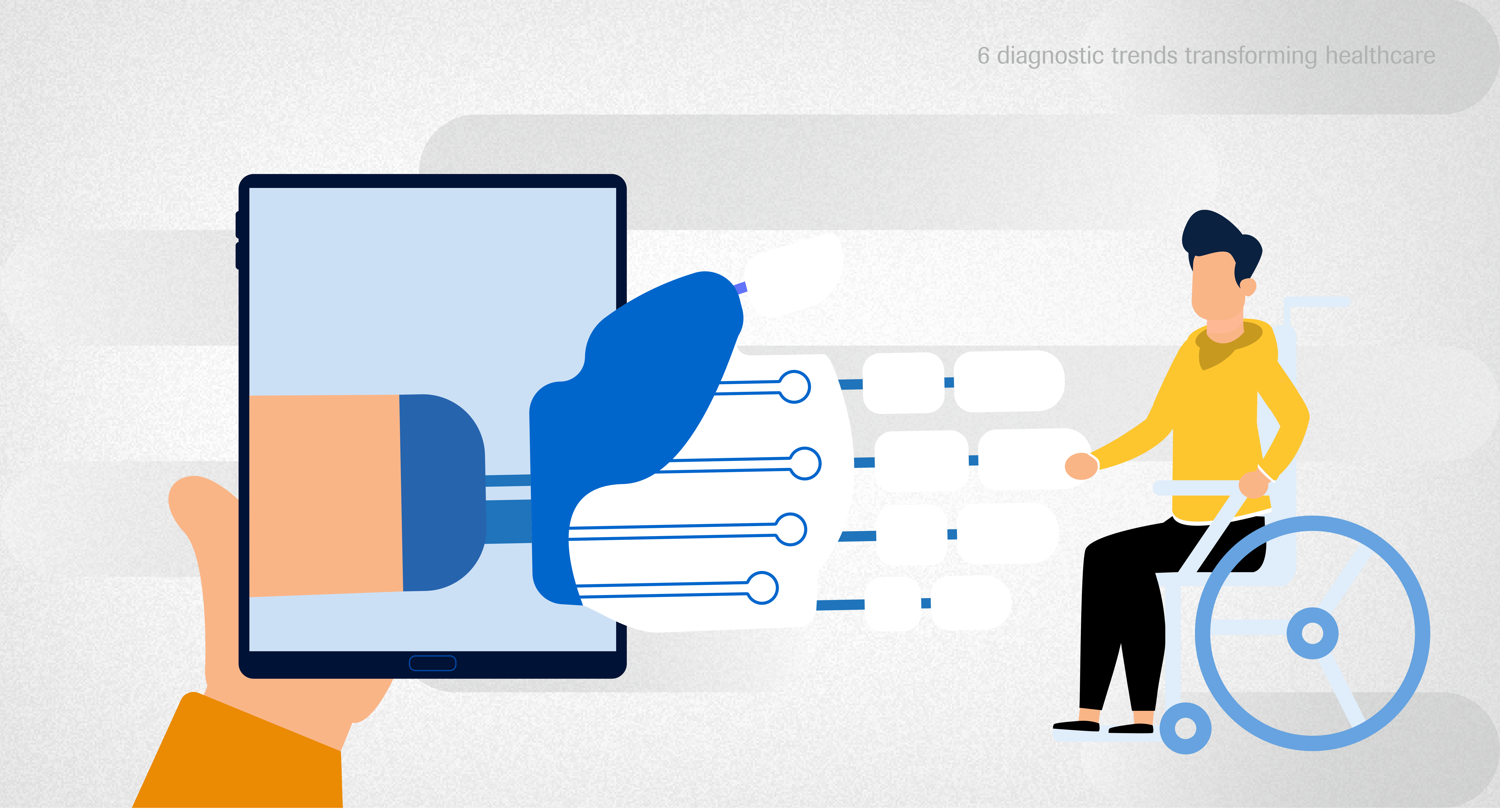


BENEFITS

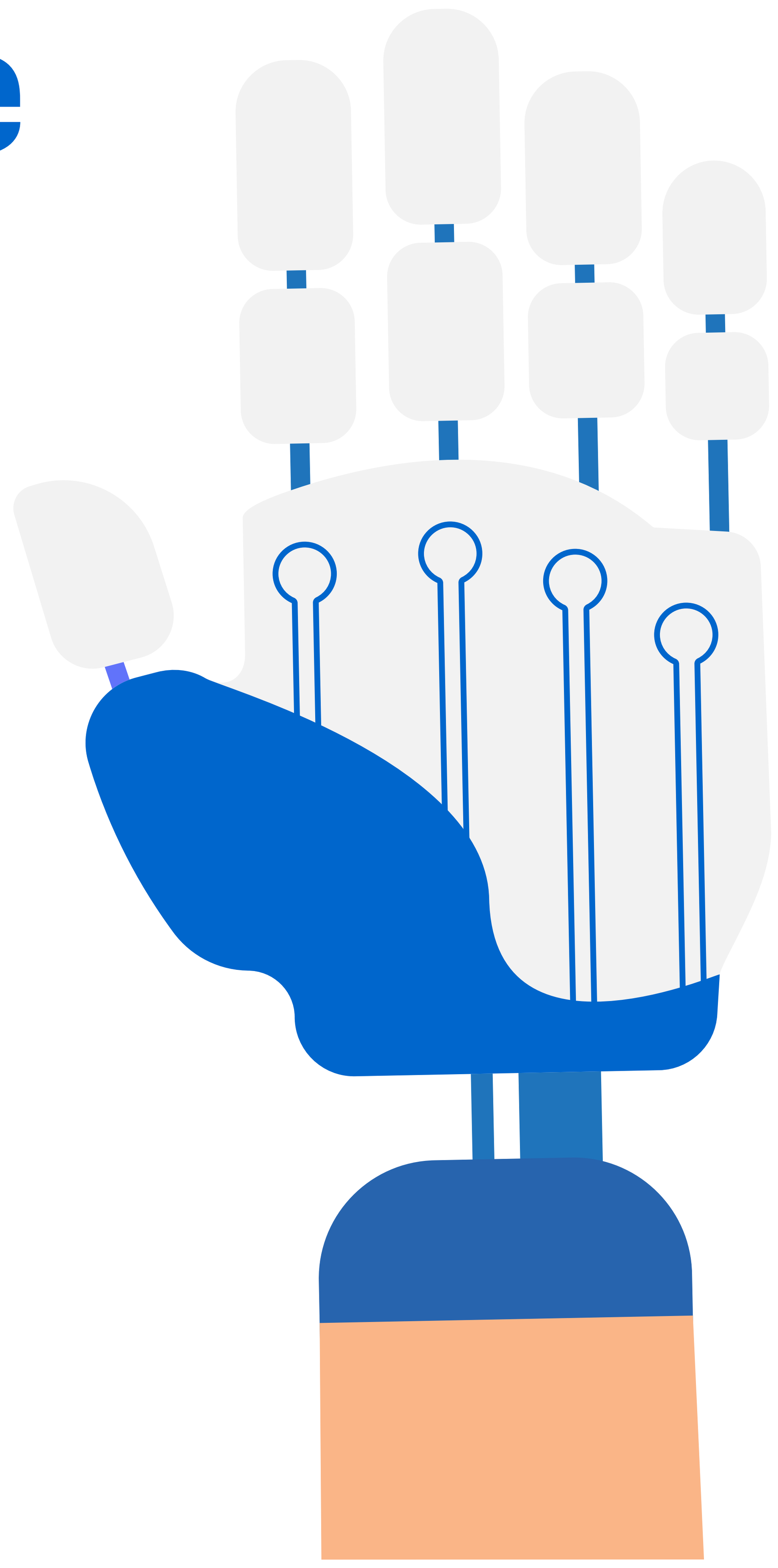
- Help reduce unnecessary testing
- Speed up results generation
- Improve profitability of labs
- Help provide better value to healthcare system
- Help retain and develop highly-qualified staff

CHALLENGES & REQUIREMENTS

- Requires significant investment in analytics systems
- Algorithms are not all reliable in their ability to predict next steps



VI. Artificial intelligence in medical imaging



Imaging is an area of intense interest and research for artificial intelligence systems, and there are already an array of FDA-approved algorithms that have diagnostic claims.[51]

A recent metaanalysis showed that the diagnostic performance of deep learning models was equivalent to that of HCP's in classifying diseases based on medical imaging.[52] Despite the highlighted concerns in the research methodologies of the individual studies included in the metaanalysis, this application of AI holds enormous potential.[52] In addition, the finding that study quality improved over time is encouraging.[52]

DISEASE AREAS WHERE AI-ASSISTED DIAGNOSTICS IS MAKING AN IMPACT

DIAGNOSING DIABETIC RETINOPATHY

There are over 126 million people in the world (as of 2010) with diabetic retinopathy, a complication of diabetes. This number is expected to rise to over 190 million by 2030.[53] According to the WHO, diabetic retinopathy accounted for 5% of world blindness.[54] It is large scale problem, but one that is solvable, since timely screening and diagnosis can help prevent vision loss. So why isn't this done more often? The primary issue is the grading of retinal images by ophthalmologists (retinal specialists) or other trained people, compared to the vast number of patients requiring screening. This is an especially acute challenge in developing parts of the world.[55]

Using IBMs Deep Learning in the Julia programming language, the ability to significantly reduce this number may be on the way. By combining Julia's superior speed and performance with IBM's powerful computing technologies, researchers were able to increase image processing speed 57 times.[56]

CARDIOLOGY

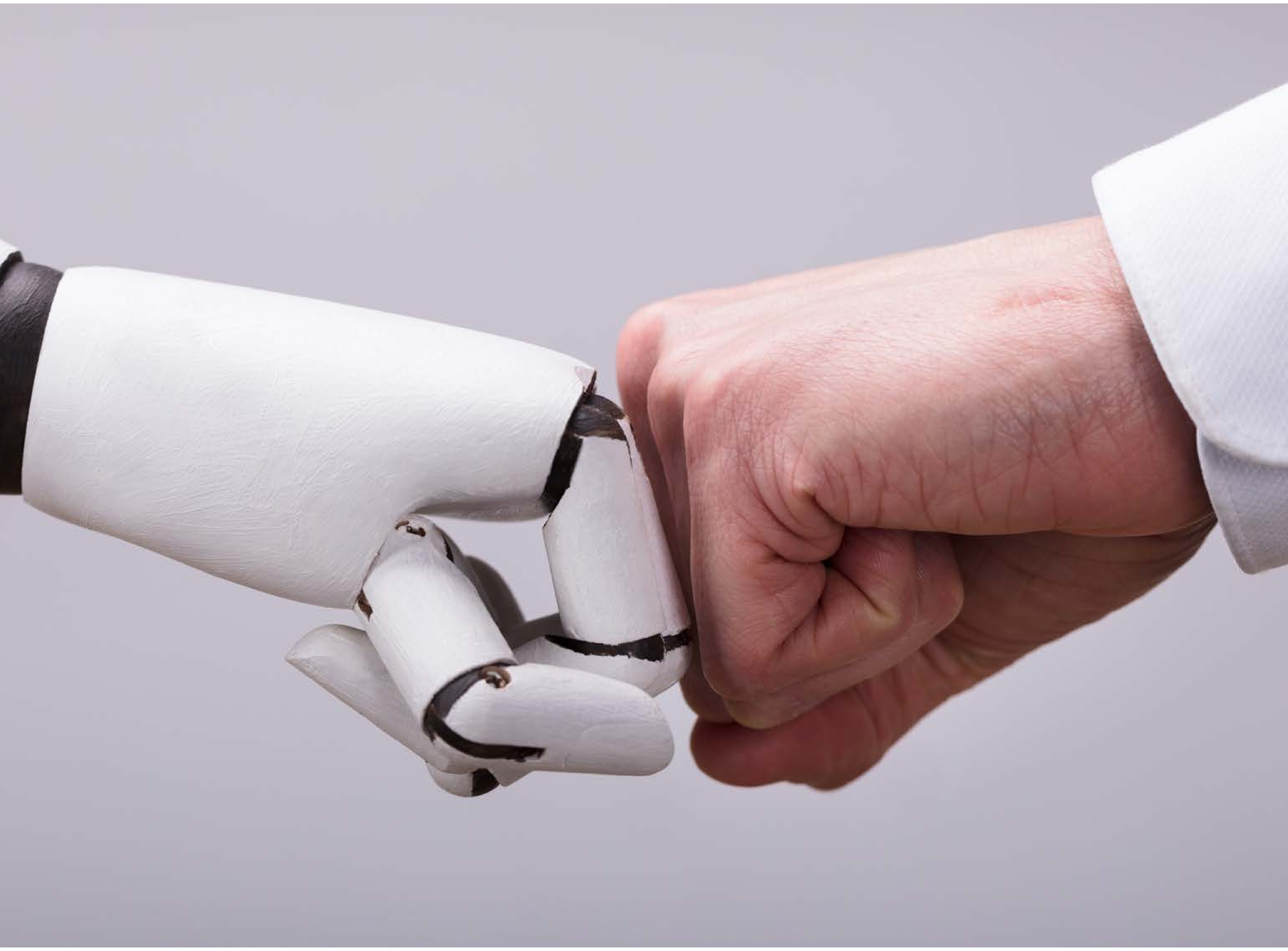
One AI systems have the potential to help doctors diagnose heart disease by analyzing images of the heart. Again, like Watson for Oncology, the tremendous leap forward here is not necessarily the accuracy of the system, which was shown to be equal to human analysis, but rather its speed: it can produce results in just 15 seconds, versus up to 30 minutes for a person.[57]

RADIOLOGY

A recent study published in Nature showed that AI-based system could not only screen mammograms to identify breast cancers at rates similar to trained radiologists, but it could even reduce errors, work more quickly and do so without any case histories to work from. By testing images where the diagnosis was already known, the AI system provided an absolute reduction of 5.7% and 1.2% (USA and UK) in false positives and 9.4% and 2.7% in false negatives.[58] Reducing these false positives and negatives is critical, as mammograms currently miss about 20% of breast cancers, causing additional tests, treatments and costs.[59]

ONCOLOGY

IBM Watson for Oncology (WFO) was developed in collaboration with Memorial Sloan Kettering Cancer Center. Recent research evaluated its treatment recommendations versus Manipal multidisciplinary tumor board in 638 cases of breast cancer. The results demonstrated that WFO may be a potentially be a reliable AI system for assisting the diagnosis of cancer, as its recommendation were 73% matched to those of the tumor board. However, this was done with a data input time of 10-12 minutes, and a median of only 40 seconds to capture, analyze and give its treatment recommendations. This means there is tremendous potential to add an AI tool like WFO to assist cancer boards and oncologists in cancer centers to determine the best course of treatment for their cancer patients.[60]



BENEFITS

- Help tackle the backlog of scans and images
- Equivalent accuracy of diagnosis, at many times with gained speed
- Potentially increase rates of early diagnoses
- Reduce workload for radiologists

CHALLENGES & REQUIREMENTS

- Robust real-world testing still needed
- Need to address potential for errors and bias

Conclusions

Digital trends in diagnostics have the potential to transform the field of in vitro diagnostics. There are some barriers to overcome: data privacy, the role of physicians in a digital future, and overcoming “solutionism”,[61] defined as the belief that technology will effortlessly solve complex and often ill-defined health issues.

Traditional diagnostic companies have recognized this future, and are increasing their R&D spend and partnering activities in digital. It is clear that the treasure trove of data generated from diagnostics can help to improve patient outcomes by increasing the efficiency, speed, precision and interpretation of testing.

At the same time, the advancement of AI-assisted clinical decision support tools can help guide physicians deliver the best treatment available to patients based on this valuable data.

The digital revolution is also set to dramatically expand the diagnostic toolbox outside of the central lab to the doctor’s office, patients’ home, and even onto the patient themselves. This will improve monitoring, allowing better health decisions to be made based on massively bigger data sets and not just guesses based on a “snapshot” of health at a single moment in time.

Labs will also be able to better manage their testing loads, using technology to eliminate unneeded tests automatically while delivering improved value with the tests they do run.

What is really needed to make this a reality are digital solutions as part of complete diagnostic solutions to improve outcomes and help patients. That’s the real opportunity: the marriage of traditional IVD companies and major technology players. Therefore, it is imperative for the diagnostics industry to accelerate its march into digital, put the foot to the floor and go all in. They need to look for partnerships with digital or tech companies for tools and technologies of all kinds that can be integrated into complete diagnostics solutions.

Together, we can build a better and healthier future for patients.

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