



## PATIENT-CENTRIC HEALTHCARE

The role of AI and data science

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# Executive summary

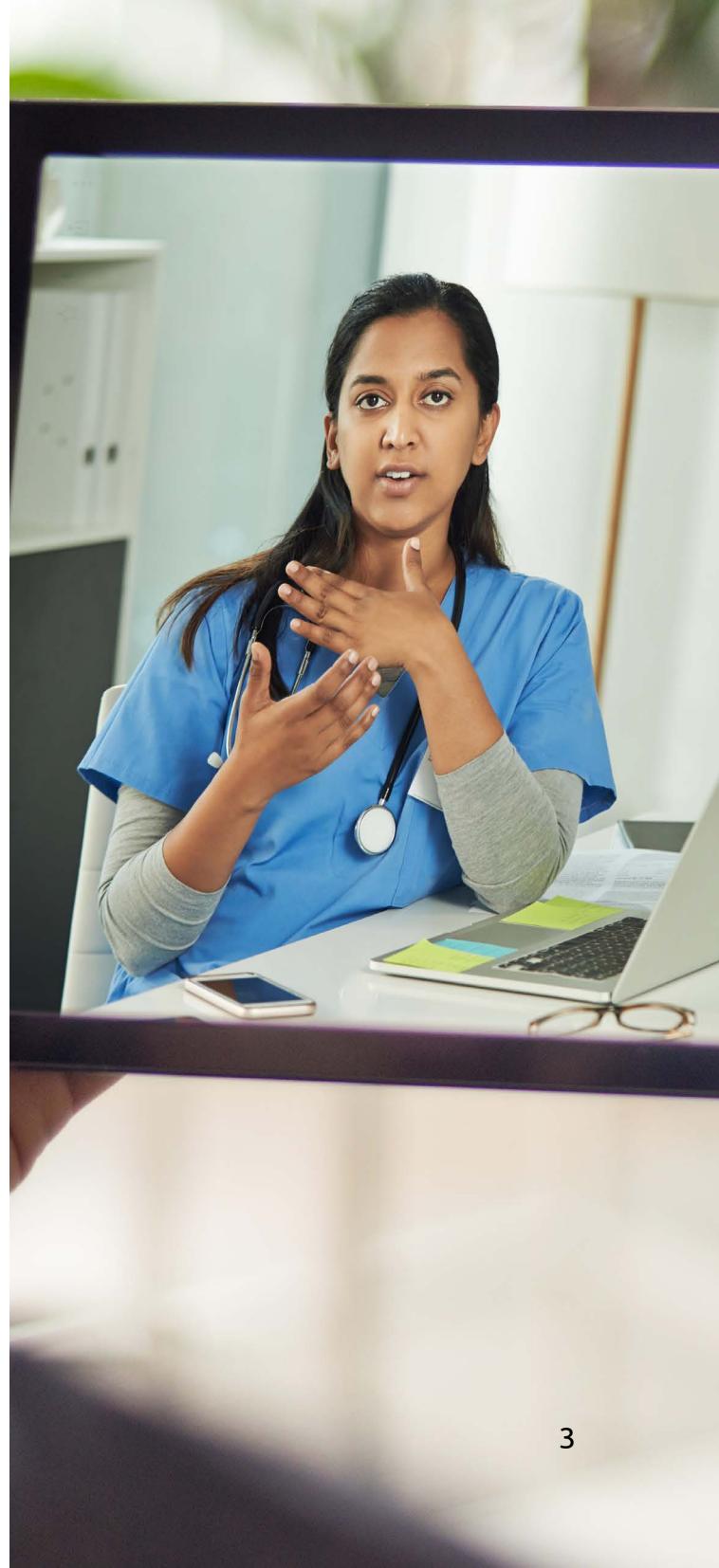
Today's consumers – including those of healthcare – increasingly expect choice and personalization. These forces are creating a huge disruptive pressure on the healthcare ecosystem.

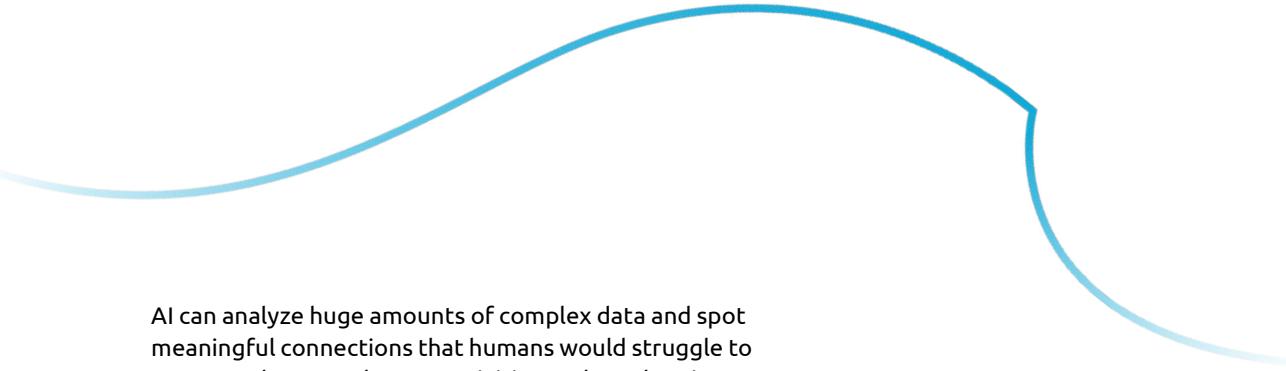
These changes – enabled by a superconvergence of companies, technology, data, and connectivity – are affecting all aspects of global business. And healthcare is no exception. Netflix and Spotify disrupted complacent industries by putting consumer needs and convenience at their center – and used clever algorithms to make mass market services more personal. The life sciences and healthcare industries are undergoing a similar shift, albeit with more complex challenges. But at the heart of this shift is the same end-user demand that is disrupting all industries – customer centricity – which in healthcare means patient centricity.

## **Profits derived from blockbuster drugs will be the first hit**

A patient-centric experience is a complex multi-faceted one. It is about personalizing drugs and treatment regimens for specific groups, adjusted for genetic makeup, lifestyle, and medical history. It's about faster and more accurate diagnoses, enabling more tailored responses. And it means a more personalized approach to remote care, and preventing illness in the first place through health and lifestyle support.

At the heart of the patient-centric revolution is the effective use of ever-growing volumes of research and patient data, and the application of artificial intelligence (AI) and data science to it. Despite the enthusiasm for AI, it is hard to do well, and there is a high risk of failure.





AI can analyze huge amounts of complex data and spot meaningful connections that humans would struggle to see – e.g., between human activities or drug chemistry, and outcomes. This is creating an increased capability to decouple complex variables and reach a far more nuanced understanding of cause and effect. This allows companies to understand what their data is really telling them and how it is affected by different situations, rather than relying on generalizations.

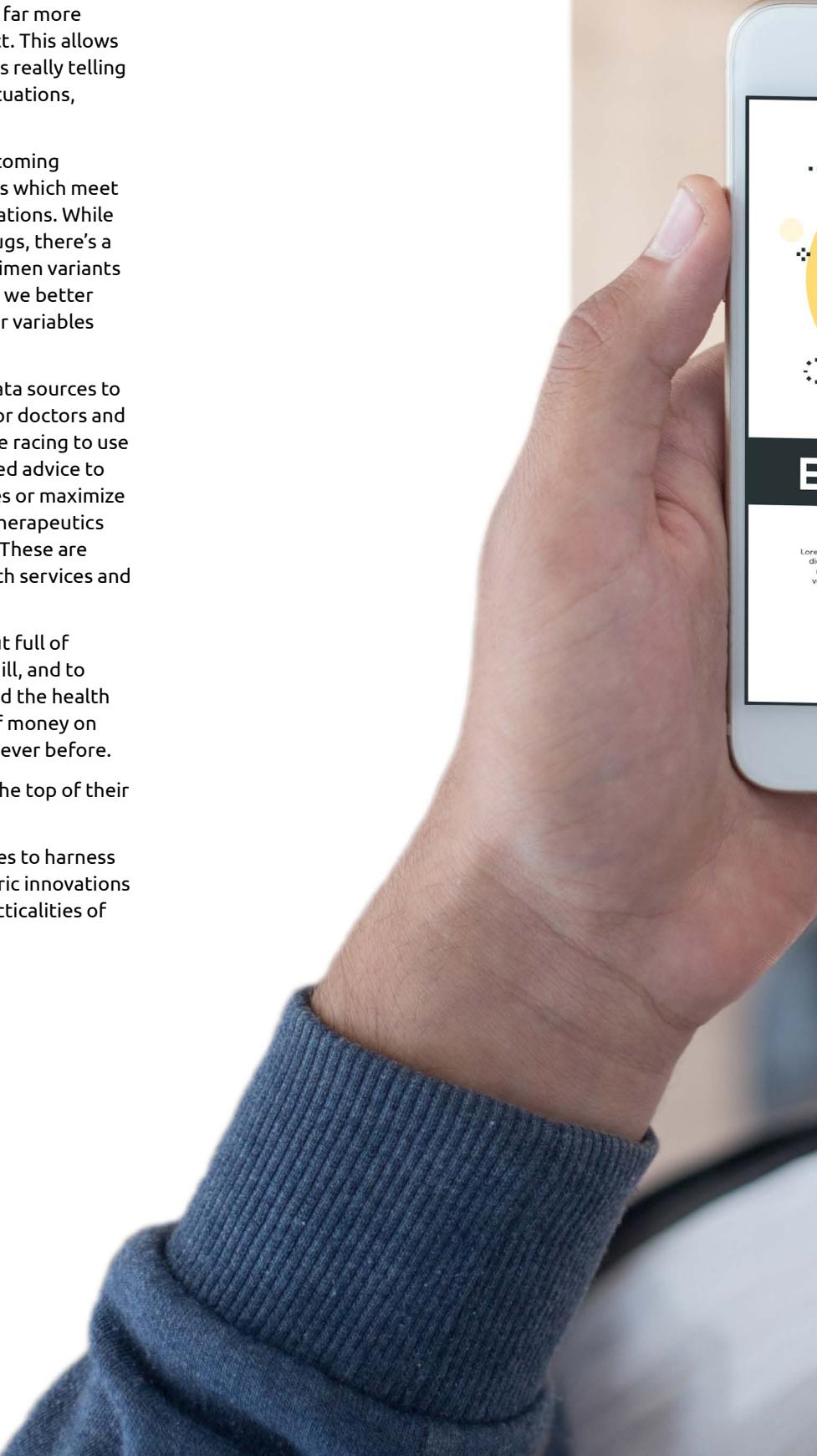
For pharma and biotech, this will mean becoming smarter with data, developing therapeutics which meet the needs of individuals rather than populations. While the future may have fewer blockbuster drugs, there's a huge opportunity to develop drug and regimen variants suited to different groups and lifestyles as we better understand how health, lifestyle, and other variables affect efficacy.

Diagnostics companies will harness new data sources to develop decision and diagnostic support for doctors and consumers. Meanwhile, tech companies are racing to use AI to develop tools that deliver personalized advice to help people lead healthier and happier lives or maximize their treatment regimens, such as digital therapeutics that aid the provision of an app with a pill. These are attracting considerable interest from health services and insurance companies, as well as end-users.

This changing world will be challenging, but full of opportunities. People want to avoid being ill, and to minimize the impact of ill health. They – and the health services that support them – spend a lot of money on both. But they also have more choice than ever before.

The industry needs to keep innovating at the top of their game to stay competitive.

This whitepaper discusses the opportunities to harness AI and data science to deliver patient-centric innovations across the value chain and explore the practicalities of building and deploying AI in this context.





# What's driving patient centricity?

The health sector is made up of a wide range of organizations. Pharma, biotech, and medical device and diagnostics companies exist at one end, and health services, private hospitals, and insurance companies at the other. Recently added to this mix are a huge number of tech companies offering new solutions to both.

Before we explore how AI and data science can benefit these different industry verticals, we'll briefly look at the global trends driving change across healthcare. These trends are interwoven and represent a superconvergence that cannot be viewed in isolation. Companies will need to move beyond the traditional healthcare industry model and integrate their capabilities and technologies, innovating together to meet patient demand, drive better patient outcomes, address reimbursement challenges, and address the disruption required. Companies who have traditionally created products to sell to healthcare providers must now consider the end-user too. They must be able to extend their business models from B2B to B2B2C. This will be a new mindset for many.

## Consumer choice

Consumers have increasing choice and on-demand access to film, music, banking, and mobility, and they expect more of it in healthcare. They have ever-increasing information to help them understand their own bodies (not all high quality), and 80% of American internet users have searched for a health-related topic online<sup>[1]</sup>. Apps offer personalized health plans. Home testing kits offer rapid diagnoses, which some see as complementary, or an alternative, to doctor diagnosis. Future patients are likely to be more questioning and have higher expectations, but also be open to new approaches.

## Preventative healthcare

Patients prefer not to be ill, and to live more comfortable lives when they are. At the same time, it is expensive to evaluate and treat patients and maintain them in hospitals. So, there's a growing drive to reduce people's need for care; healthcare services will increasingly move from hospitals and clinics to homes and communities over the next decade<sup>[2]</sup>. As the connected world opens channels for remote care, evidence-based approaches that keep people from becoming ill or make conditions more manageable are likely to see an increased uptake.

## Precision medicine

There's a growing interest in treating subgroups rather than one-size-fits-all approaches. With more data and better tools to pull it apart, we can predict and measure how variations in drug chemistry or treatment regimens affect different groups depending on their genetics, age, or lifestyle. This will allow companies to capture sections of an existing market by providing them with more effective treatments.

## Digitalization

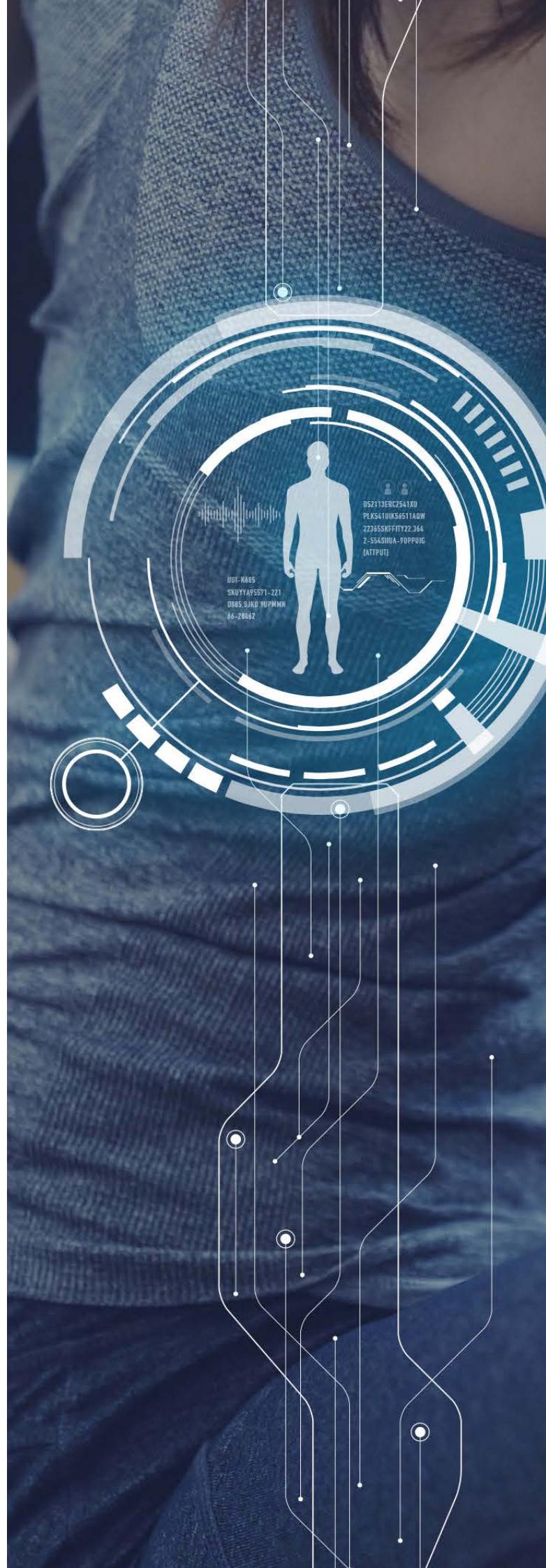
Wearables, sensors, and mobile technologies capture ever more data, allowing for example, patients to take part in clinical trials through smartphones in a way they never could before. This allows unprecedented insight into the health of individuals, and unprecedented ability to develop targeted new products and personalized healthcare plans. The associated connectivity of these devices opens up new possibilities to monitor effectiveness and side effects, and nudge them towards good behaviors, from healthy lifestyles to drug adherence.

1. NBC, 'More people search for health online', 2003, available from: <http://www.nbcnews.com/id/3077086/t/more-people-search-health-online/>

2. Monitor, 'Moving healthcare closer to home: Summary', 2015, available from: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/459400/moving\\_healthcare\\_closer\\_to\\_home\\_summary.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/459400/moving_healthcare_closer_to_home_summary.pdf)

## Storage and processing power

Machine learning, a subset of AI, has long been used in R&D. But advances in algorithms, and new and more sophisticated tools, are adding the ability to tackle more complex and ambitious tasks. These advances have been made possible thanks to the explosion of data that's available to process, the ability to store it, and the exponential increase in computing power.



# AI in healthcare: the wild west

AI classifies data based on the relationships between many different interconnected factors. Unlike traditional software, which follows rules defined by software engineers, AI automatically formulates the rules from the data it is trained with. So, an AI model fed large numbers of images of different skin rashes can learn to spot each type based on their unique combination of characteristics without being told what a particular rash looks like.

It can also find new links; e.g., a model can be told what a pharma research is trying to achieve, then analyze molecule libraries to identify likely candidates without being explicitly trained on what to look for. In some cases, this can lead to approaches that no human would see. NASA used generative algorithms to design an antenna against a set of criteria – the result would never have occurred to a human but was better than anything a human came up with. Similar approaches are being used in drug design.

AI is also good at isolating complex variables. For example, an AI can model the implications of multiple drug regimens. For humans looking at patients taking multiple drugs, it would be too hard to isolate all factors and conclude that a particular interaction was having an adverse effect. But this is where deep learning shines. With enough data from large populations, AI can spot weak signals that show how and when specific combinations of factors lead to specific outcomes.

Right now, AI is like the wild west: a land of massive opportunities but with a lack of rules and oversight. The risk is that progress will be slow and chaotic.

That's not to say that there are no successes. There are plenty of excellent examples of AI delivering value and many promising application areas. However, without structure and agreement on productive ways forward, progress will be patchy at best. AI at scale requires the right data, models, training, deployment, and governance structures to be in place.





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Drug-related adverse events from medical devices or pharmaceutical products. These include side effects, allergic reactions, and other adverse events related to the use of drugs or pharmaceutical products. This category also includes reports of drug-related adverse events from medical devices or pharmaceutical products.

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The Internet of Things (IoT) refers to a network of physical objects that are interconnected and can exchange data over a network. These objects can be anything from simple sensors to complex systems, such as smart homes, industrial equipment, and medical devices. The IoT is often used to describe a wide range of applications, including smart cities, smart grids, and smart homes. The IoT is also used to describe a wide range of industries, including healthcare, manufacturing, and transportation.

# The cross-cutting impact of digitalization, AI, and data science

Patient centricity is driving change across all areas of healthcare. Ensuring AI and data science can deliver the outcomes expected will be key at a program and project level. In this section, we will look at real examples of where AI and data science are delivering impact in three major areas – including several that Capgemini Engineering was involved in – and assess how we can help AI move from a technology trigger to a real force for productivity.



## How do we seize the opportunity?

### Examples of AI and data science delivering impact in patient-centric healthcare

Disruptive discovery and clinical innovation	Decision support and AI diagnostics	Smarter healthcare and well-being
Comparing medical literature and genetic data to find clues about gene-disease associations and identify new targets	Spotting indicators of likely presence of a disease in medical images	Using patient monitoring devices to recommend individual treatment and lifestyle plans
Using precision medicine to predict who a drug will work for	Matching symptoms or tests to medical literature to validate diagnoses	Designing personalized treatment regimens based on metabolism, lifestyle, co-treatments, and adherence
Re-evaluating clinical data to spot where a drug showed promise in areas studied	Matching genetic tests to databases of rare diseases to unusual diagnoses	Using in-home devices to help patients manage conditions
Using AI on on-body sensors data to understand drug performance in different groups	Using 'digital biomarkers' such as images of skin conditions or cough recordings for smartphone diagnosis	Delivering personalized health, diet, and lifestyle advice delivered through simple apps

### Key challenges

Scientists look for empirical evidence in discovery research. It will be key to ensuring that when AI is used, it is readily explainable to aid acceptance. What is the best path to achieving this?

Do you know what data you need to capture in order to support the chosen AI and data science methodology and ensure you take the right decisions?

Is your AI approach validated and regulatory compliant? Do you know how to industrialize it?

## CASE STUDIES

# Disruptive discovery and clinical innovation

AI can look for hidden patterns in complex sets of diverse data – from chemical analysis and past clinical trial data to user feedback – and spot insights that will guide more focused and targeted drug development.

### Detailed patient data from clinical trials

Many clinical trials of ongoing drug regimens require regular check-ups. But patients often behave differently under observation, which can skew results. For a new arthritis drug, a major pharma company is using medical-grade sensors to assess people in their home, and measure factors such as speed of movement and transitions, which they can then link to drug performance. By applying AI, it is possible to establish baseline patterns of behaviors and spot subtle improvements.

### Peace of mind about skin cancer

SkinVision checks for signs of skin cancer using your phone camera with instant results. Trained on large databases of skin cancer images, its AI can spot suspicious signs which should be checked by a specialist. Such image analysis relies on very subtle physiological correlations, which would not be possible without AI.

### Decoupling effects of stress from drug research

Verum, designed by Cambridge Consultants, is a wearable which remotely monitors stress levels. It monitors voice and electromyography (EMG) and applies machine learning to predict stress levels. Since stress can have an impact on drug efficacy, this allows researchers to understand the impact of stress during trials, which in turn allows it to help support patients and improve trial design to decouple the effects of stress from its results.



## CASE STUDIES

# Decision support: personalized evidence-based diagnostics

AI can spot patterns in complex data – such as medical images or sample analysis – that are indicative of a specific condition. It can also compare symptoms to medical databases, expanding the range of considerations beyond any single doctor's experience.

### Precise rapid diagnosis of infectious disease

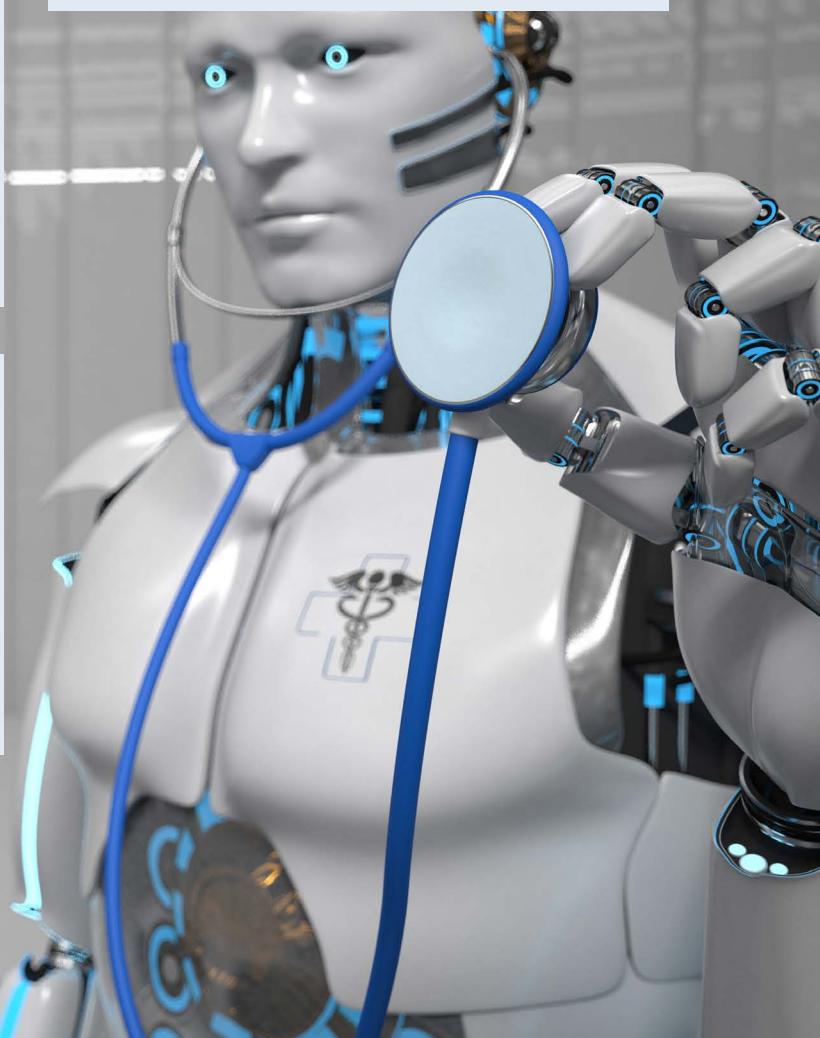
Stat-Dx checks for every possible pathogen of a specific syndrome in an hour, allowing a rapid diagnosis. Usually, such tests involve sending samples for lab analysis, meaning effective treatments are delayed, or incorrect antibiotics prescribed. Stat-Dx's platform, which has since achieved regulatory approval, applies a chemical process to the sample, which amplifies pathogens and causes them to fluoresce. Sophisticated algorithm and software techniques were developed, with support from Capgemini Engineering, to link the fluorescence pattern to the presence of a specific pathogen, achieving diagnosis accuracy of more than 98%. The system gives doctors a rapid diagnosis of the exact infection, allowing them to prescribe the right treatment immediately.

### Diagnosing gastrointestinal disease by the smell of your breath

SniffPhone is investigating using a small plug-in module for a smartphone that can detect disease from exhaled breath. Breath samples are digitized and key parameters are compared to the app's database to detect subtle indicators of a wide range of gastrointestinal diseases, including various cancers.

### Diagnosing respiratory disease by the sound of your cough

ResApp uses a microphone to listen to coughs and identify different types of respiratory disease. A machine learning app trained on a large dataset of coughs linked to different diseases can distinguish between different types. It is currently used by clinicians to support diagnoses but may be rolled out to consumers in the future.





## CASE STUDIES

# Smarter healthcare and well-being

New sensor and communications technology such as smart watches allow data to be collected on people as they go about their lives. AI can learn from this data at a granular level to understand how healthcare approaches affect different individuals, and this can be used to make recommendations to optimize healthcare regimes or promote healthy living and disease prevention.

### **Improving quality of life for diabetics**

M4P, a French project led by Capgemini Engineering, is establishing the Diatabase, which is capturing information on the life and health of diabetes sufferers via data directly uploaded by patients and their healthcare professionals. As the database builds, it will establish how a patient's environment affects disease progression, treatment effectiveness, and impact of other diseases. With added analytics and interfaces, this will allow doctors to identify optimal, personalized treatment and lifestyle regimens. Once proven with diabetes, the same architecture can also be used for other diseases.

### **Personalized nutrition and weight loss based on your metabolism**

Lumen is a metabolism measurement device integrated with coaching algorithms. It measures your breath to understand individual metabolism based on the gas composition. It can then deliver personalized weight loss and fitness advice based on what your body needs at that moment, rather than one-size-fits-all plans.

### **Blood pressure monitoring and health advice from your phone**

Riva Digital uses a smartphone camera to measure the color of blood flowing through your fingertip and deduce blood pressure. Using AI, it can sense very slight variations in color and link them to pressure. The first version of the app warns of danger signs, but future interrelations will augment this with healthy living advice. Further AI could be applied to monitor diabetes (via changes in blood flow).

# Smarter healthcare outcomes: two use cases for delivering AI in practice

Some organizations are already delivering successful AI projects. Here, we look at two projects Capgemini Engineering supported and explore how the company approached planning, data gathering, model design, and project delivery to produce tangible outcomes that had a demonstrable business benefit.

## Use case 1: AI-enabled drug design

A major pharma company is investigating how AI can improve its drug design process.

A common drug design approach is to use a higher level description of what we want a molecule to look like. One such description is the reduced graph, which involves specifying in chemistry terminology what structure the molecule should have, for example, “an aromatic ring connected to a linker, which in turn is connected to an aliphatic ring acceptor, which in turn will potentially be connected to several other molecular substructures with different characterizations”.

This high-level description is useful because it limits the search for molecules to those which meet specified criteria, i.e., having a similar structure to a known active compound. Creating a reduced graph for a known molecule is easy; the bigger challenge is the opposite process – finding good potential molecules which match the desired reduced graph.

It's a bit like buying a house: if your criterion is any house, you will never find what you're looking for. But if you specify location, number of bedrooms, and price, you have a better chance. Specifying the reduced graph of a molecule is like providing a detailed layout for your ideal home. However, while there are a million or so property ads online, the number of molecules available for drug design is around  $10^{60}$ , with the overwhelming majority never having been synthesized. This challenge of generating a set of candidate molecules from a reduced graph description is something AI can help with. Remarkably, we found that this problem can be related to a completely separate AI challenge: translating languages.

Language translation takes advantage of two cutting-edge developments in neural networks: sequence-to-sequence learning and attention mechanisms.

Sequence-to-sequence learning takes a sequence of words – a sentence in English – and outputs another sequence of words – a translation in French. Languages have very different structures, which is why successful machine learning approaches consider sentences in their entirety and generate a new sentence which captures the whole meaning.

It's, of course, also useful to know that particular words in each language relate to each other, and this is where the attention mechanism comes in. Attention mechanisms allow the model to focus on particular words in the input sentence when generating particular words in the output. Together, this allows translations in which the right words are selected, but also capture the correct overall meaning.

A molecule can be represented as a text sequence using a SMILES string. The same is true of the high-level reduced graph capturing the outline of what the molecule should look like. We created an approach that applied the same basic principles of language translation to translate the outline of a molecule into a specified novel molecule matching the outline. In other words, to predict a molecule to match our requirements.



All we required was a dataset with hundreds of thousands of molecules and their equivalent reduced graph outlines to train the AI system. Fortunately, there are huge datasets of molecules that are readily available, and generating high-level descriptions of a complete molecule is relatively easy. For any given reduced graph, the AI can propose new molecules which match the specification, which chemists can use to guide their search for the next drug candidate.

To validate the model, we fed in high-level reduced graphs of drug candidates from published literature – i.e., with existing answers – that the system had not seen. If the AI could take these high-level descriptions and generate a known active compound, this would be a great indication of its value in future discovery programs. In work published in the *Journal of Chemical Information and Modeling*, we performed this test with 20 different known active molecules. In most cases, a known active compound was generated, and in all others, molecules generated were similar to a known active compound.

Such approaches can benefit all aspects of drug design. As drug research becomes more personalized, the ability to reduce time finding the right molecules will become increasingly valuable<sup>[3]</sup>.

Peter Pogány (GSK), Navot Arad (GSK), Sam Genway (Capgemini Engineering), Stephen D Pickett (GSK)

3. ACS, 'De Novo Molecule Design by Translating from Reduced Graphs to SMILES', 2019, available from: <https://pubs.acs.org/doi/10.1021/acs.jcim.8b00626>

# Smarter healthcare outcomes: two use cases for delivering AI in practice

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## Use case 2: digital diagnostics and AI

### Quick and accurate diagnosis saves lives

At six days old, Maverick Coltrin developed seizures. Doctors were baffled, his parents feared for his life, and conventional diagnostics had failed to reach a conclusion. The medical team at the Rady Children's Hospital suggested Maverick take part in an innovative digital diagnostics study. The approach used data gathered from the latest genetic sequencing techniques, then applied artificial intelligence (AI) to match it to existing research and diagnostics information sources about rare genetic diseases.

The results came back, showing that Maverick had a rare form of epilepsy, but one that was easily treatable with vitamin B6 supplements. His life was transformed. The technique used to diagnose Maverick is part of a growing field of digital diagnostics made possible by the combination of sophisticated AI and the ever-increasing availability of genetic and patient data.

### Why the time is right for AI-assisted diagnostics

These new approaches to diagnostics are possible because of the ever-increasing availability of data and sophisticated low-cost AI tools. Every year, the cost and time to produce genetic sequencing data become more economical and faster than the previous year. Patient electronic medical records (EMR), digital scans, and digitized research outcomes now become more readily available than ever. The most advanced AI tools ever developed are widely accessible in an open-source format and often pre-installed on powerful yet reasonably priced cloud platforms.

### The secret sauce

It is essential to understand that developing AI diagnostics systems is not as straightforward as just combining cutting-edge AI technology with vast quantities of data. Generating insight from clinical and healthcare data is challenging work; it needs medical science expertise, world-class data science technology, and talent, as well as the IT experience to integrate emerging and novel technologies into robust operational systems.

The vast history of medical literature and genetic data does not present itself in an easy to navigate spreadsheet – but appears in many different and complex formats, from research papers and handwritten notes to images. Comparing and extracting this kind of data demands a highly specific approach to the design of AI and machine learning algorithms. This kind of work is far removed from the world of e-commerce or consumer AI, where simple correlations can deliver a good enough return. The need for the highest accuracy and a rigorous proof of causation from complex datasets requires a very different breed and blend of data science.

In this field, much of the work utilizes deep learning, a form of AI whereby the model learns to interpret relationships in large and complex sets of data. Presented with enough data, it gradually learns to identify what is essential and how information relates to each other. It typically involves training a multi-layer artificial neural network on a labeled dataset. With enough training data, a well-designed deep learning model will classify information as accurately as human experts, in a fraction of the time. Other advanced AI and machine learning techniques may combine several models together to create sophisticated learning capabilities that, when applied



to a variety of data sources, produce highly accurate predictions.

### Who is doing it well?

Many organizations are doing this well. For example, a system developed in a collaboration between the Manton Center for Orphan Disease Research, part of the Boston Children's Hospital, and Alexion is able to produce a highly personalized sequence of clinical questions to aid diagnosis of rare diseases. This system combines the diagnostic knowledge of healthcare professionals, a global disease database, and the specifics of a patient's personal medical history to go through a series of questions that narrow down the highest likelihood indication step by step.

The resulting AI platform, developed by Alexion with their affiliates, uses various AI algorithms including the 20 questions game format. This platform has the potential to place the global knowledge of rare diseases into the hands of every clinician. They then combine this with their personal experience and expertise in patient interaction to significantly increase the probability of diagnostic success. Rare diseases present a specific challenge to AI systems – AI systems need large quantities of data to learn from, but by definition, large datasets are not available for rare diseases.

Another Alexion affiliate, the Rady Children's Institute, has gone even further, leading it to receive a Guinness World Record for a rapid under 24-hour diagnosis using genome sequencing as an input to the AI diagnosis. An AI engine analyzed the digitized results and identified the overlap between the specific observations of a given child's illness with a reference set of expected observations covering all genetic diseases. The key to the automated diagnosis is combining genome sequencing, phenotypes, and natural language processing. The patient's electronic

medical records (EMR) are processed to identify and extract observed disease features; these are then compared with the results of genetic sequencing.

In this race against time, the manual review of health records takes precious hours from an overloaded medical professional and is prone to personal subjectivity. AI diagnosis support, which combines the evidence in the gene sequence and health records, not only reduces the elapsed time, but can also combat this bias.

### Future AI diagnostic

Companies such as Alexion, working with their affiliates, are looking to bring AI-assisted diagnostics to an ever-wider range of diseases. They will look to make greater use of phenotypes and genetics data to reach this goal.

The challenge for the Alexion data sciences team, and those like Capgemini Engineering working with them, is to master and integrate an extensive range of highly specialized algorithmic techniques known under the generic term of AI. This challenge has been met through an active collaboration between internal and external data scientists working closely with physicians and healthcare experts. New specialists are able to join the core team rapidly and communicate clearly how complex technical choices will play out to the medical, business, data, and IT subject matter experts.

### Conclusion

Thanks to AI diagnostics, new levels of speed and accuracy are possible, helping doctors make correct diagnoses and expanding the likelihood that they will spot more unusual conditions. The upshot will be faster interventions and increased accurate diagnoses. This will reduce costs of readmissions and increase the chance of initial treatments being successful. Most importantly, it will save lives.



# How to deliver AI and data science projects

This whitepaper has highlighted the potential for patient-centric healthcare and both the critical roles of AI and data science in delivering it, in addition to the questions we should be asking ourselves.

Exploring the potential of AI in an organization comes with significant challenges, as does industrializing it. In the final section of this whitepaper, we provide a guide to building and implementing AI, to support the journey to patient centricity.

## Get the planning focus right

### Decisions first, data last

Start by defining what you are trying to achieve. Successful AI programs start by identifying the decisions needed to solve problems. They should ask how those decisions – whether they are human or automated – could benefit from greater insight and what that insight might be.

Only then start identifying what data you need to deliver. Sticking sensors in and seeing what insights data throws up may yield some results, but it is unlikely to be cost-effective and probably won't give you the results you want. Instead, plan to capture the data you need to drive decisions.

### Stay agile

While you need to know what you are trying to achieve, in the uncharted landscape of AI, heavy planning, long development cycles, and huge investments, all increase risks. Successful AI pioneers have a clear objective but explore different approaches through agile iterative real-world experimentation.

### Take a joined-up approach

Ensure everyone understands what they are trying to achieve, not just what they are doing. In large complex organizations, it's common to assign actions without understanding. For example, a department will be told to set up sensing devices to capture data during a clinical trial, without fully understanding how that data will be used. Years later, the data team will come to that data and find it isn't what they need.

## Employ the right expertise

AI is complex and needs people, not just technology. These are new techniques and often, companies don't have the specialist skills to harness them.

Successful AI projects need knowledge of relevant AI techniques (of which there are many), and of devices and data. They also need domain expertise to bring an understanding of what the data means in the real world, e.g., biochemical interactions or human biological functions. And in the patient-centric world, they need experts who understand what this means for patient quality of life.

This path from data collection to meaningful human outcomes must all come together, which means also employing translators who can bridge the language gap between the different experts – physicians, chemists, businesses, doctors, carers, and patients.

## Build trustworthy AI

### Capture the right data

Health data is complex, varied, and often poorly structured. It is a mix which includes data from chemistry and biology, genetics, human activity, medical images, medical notes, and electronic health records. To get good results, you need good data fed into the model.

Some of this is challenging to capture reliably. Handwritten doctors' notes can be hard to accurately digitize. Data from consumer smartphones introduces risks from uncontrolled variables, firmware updates, raw data, and poor quality data. This can still be useful data – top-end smart watches have very good data collection – but it's important to set up data collection correctly to deliver the type and quality of data you want, and to understand its limitations.

### **Validate your data**

In some cases, it is necessary to verify that your data has a real effect. For example, a wearable sensor may infer that a data pattern means the patient is stressed. But to be certain, you need to set up trials where you know the patient is stressed and ensure your measurements consistently correlate with other reliable stress indicators. This requires time and investment.

### **Ensure data compliance**

To do all these exciting things, AI needs data, and this data must comply with the relevant regulations. For example, in Europe and the UK, patient data is considered PII and protected by GDPR. For consumer applications, GDPR requires user permissions and anonymization. In the US, HIPAA provides data privacy and security provisions for safeguarding medical information. Other regulations cover specific processes, a case in point is the EU's Clinical Trials Regulation which defines how organizations record, process, store and handle data, accurate reporting and verification, and confidentiality. In our opinion, the direction of travel is for people to want control over who has access to their data and what they can do with it.

Ensuring AI algorithms themselves are compliant is increasingly important. In April 2019, the FDA released a discussion paper on an AI framework for approving medical devices which use AI<sup>[4]</sup>. It proposes best practices and expects manufacturers to provide transparency and real-world monitoring of AI devices, as well as updates as algorithms evolve. Expect this to become a rapidly evolving area of regulation which requires close attention.

### **Choose the right tools**

Armed with the right data, organizations need to identify the right tools. These could be deep learning or machine learning algorithms, or statistical models. There is no single answer; an experienced data scientist will have seen enough to know what options are best for the job, whether it is adapting previous algorithms or creating new ones. They will also need suitable platforms to deal with lots of data; these should be decided based on need, not on which tech provider has the best marketing campaign.



### **Establish causal connections**

When building AI algorithms, correlations between data and outcomes will never be enough in healthcare; there needs to be a causal connection before we can trust an AI to make decisions. This can be done, for example, by comparison to control groups to eliminate variables, or by working closely with subject matter experts who can recognize driving factors through their understanding of the underlying science.

### **Make it explainable**

Where necessary, AI should be designed to explain how the model reached its decision. If the user doesn't understand what's driving the AI decisions, they will struggle to trust the results. Explainable AI (XAI) involves designing systems with provision for interpretation and understanding of decisions. This is an actively developing research area.

### **Deployment and operational success**

#### **Validate your models**

Trusting that the AI works is essential, which means careful validation of algorithms before they are used in the real world. This can involve various processes such as running the model on well-understood new data to check it reaches the right conclusion, independently checking the code, or having medical experts assess the results and confirm they make sense. This is even more important where AIs are too complicated for full explainability to be built in.

#### **Consider how to operationalize from the start**

Data scientists are getting pretty good at developing sophisticated AI models in the lab, but these often fall over when deployed into a real-world operational or consumer environment. AI is not just about the model – that model must integrate with other IT or operational systems. It must be designed with its eventual deployment in mind, considering cloud architecture, DevOps, user interfaces, etc. Consult with both users and IT teams early on to understand these challenges.

### **Focus on user experience**

Ensure your AI is designed to be easy to use or people won't use it. Healthcare product manufacturers are used to selling to doctors and expect them to just get on with it. With a growing expectation of easy-to-use technology, this is no longer enough. We can't expect people to engage with second-rate user experience, and this is doubly true where the end-user is a consumer – e.g., a platform to upload self-reporting on drug trials or support long-term conditions. The ultimate aim of AI is to act as a collaboration partner to the human, to inform decision-making, and generate trust in its data-driven conclusions.

### **Deploy gradually and continually assess**

Some AI deployments will need to be done specifically to test them in real-world healthcare environments to gather enough data to train them and improve their accuracy. For example, Deepmind's Streams, a tool to diagnose kidney disease, is being trialed by the UK's National Health Service (NHS). This approach also allows the AI to evolve in the real world, where doctors can flag when they disagree with a decision, which can help the AI learn.

It will take time for people – including professionals – to trust a machine with healthcare decisions. Don't expect immediate results. AI systems need to be rolled out gradually with checks until they are proven. For example, a doctor may start by making her own diagnosis, then run a diagnostics AI to validate it, or consider other options. Over time, she may trust the AI on its own and make diagnoses in parallel. And eventually, the AI may be the first port of call, with the doctor being brought in only for serious or edge cases.

Expectations need to be managed as AI use grows. AI has huge potential, but it needs time to learn in the real world and to win over sceptics. Overpromises early on can lead to long-term suspicion, as IBM Watson found.

Analyzing the skin

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## About Capgemini Engineering

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