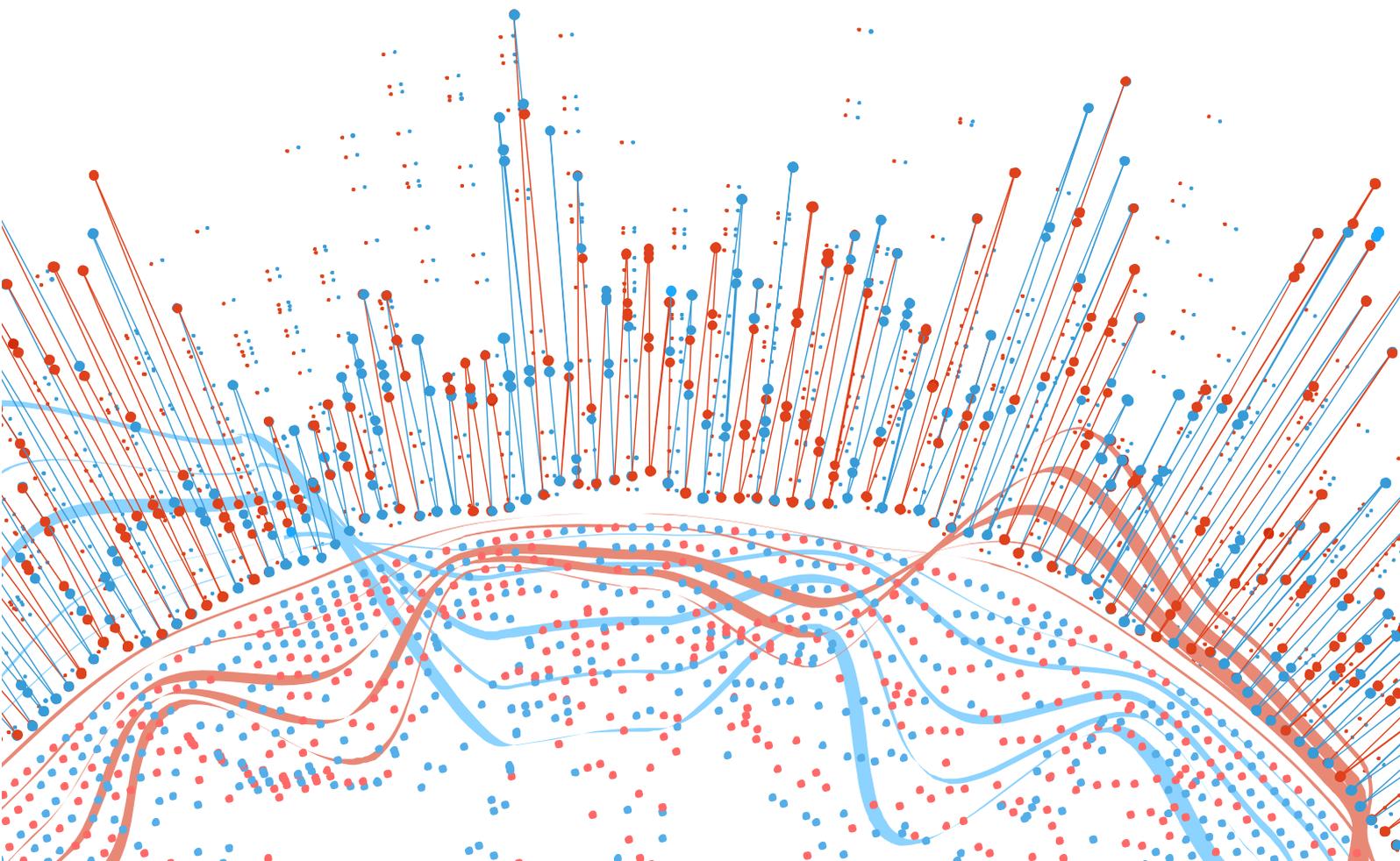
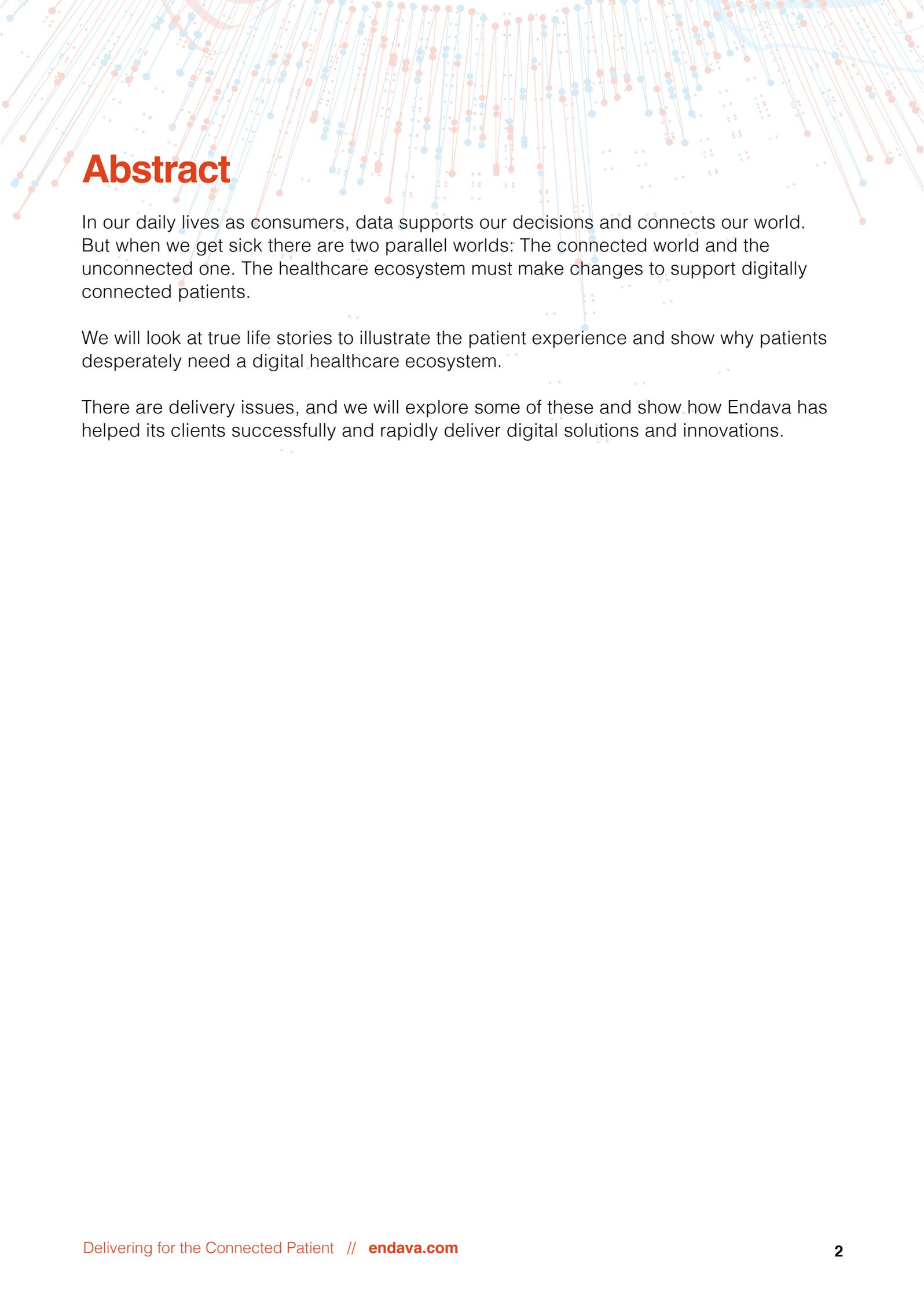




Delivering for the Connected Patient

**Accelerating Digital Transformation for
Improved Patient Experience**





Abstract

In our daily lives as consumers, data supports our decisions and connects our world. But when we get sick there are two parallel worlds: The connected world and the unconnected one. The healthcare ecosystem must make changes to support digitally connected patients.

We will look at true life stories to illustrate the patient experience and show why patients desperately need a digital healthcare ecosystem.

There are delivery issues, and we will explore some of these and show how Endava has helped its clients successfully and rapidly deliver digital solutions and innovations.

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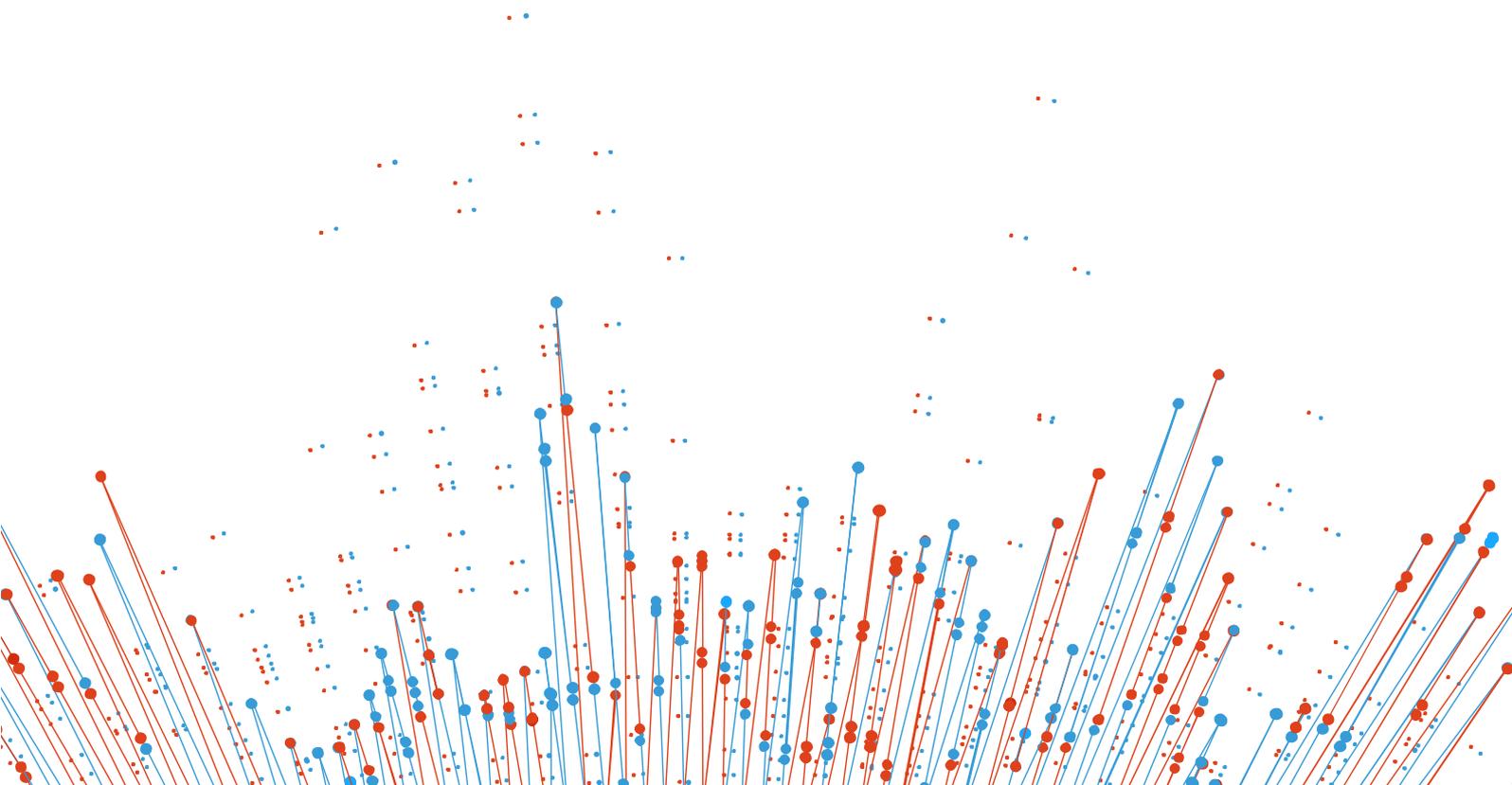
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Introduction

The drivers in healthcare for accelerating the adoption of digital technology have, in the past, been balanced with technical and organizational issues that have led to delays and put healthcare digitally behind other areas of life. In our lives as consumers, data supports our decisions and connects our world. But for patients there are two parallel worlds: the connected world and the unconnected one.

Clinicians and patients have learned through the pandemic that, for example, remote consultations and treatments are not only possible but are in many cases preferable – and are pushing for further digital adoption to a more connected healthcare. Virtual visits are safer from an infection control perspective; they are less costly, enable a higher degree of provider/caregiver productivity, and may even help address the burnout issues of clinical staff.

Beyond the patient, the wider healthcare ecosystem is focused, now more than ever, on delivering new digital care models - and is now looking for rapid digital adoption. However, there are still issues with delivering the technology.

What our clients have found is that delivering digital healthcare solutions requires much more than just access to engineering teams. It goes without saying that skilled and trained engineers are essential, but on top of that processes and controls that ensure regulatory compliance and safety are needed. Healthcare specific integration experience is vital, as are UX/UI designers who can ensure solutions engage patients, and safely support clinicians. And finally, deep knowledge of AI and machine learning is required if the full potential of digital healthcare is to be realized.

We have helped our clients by meeting these needs.

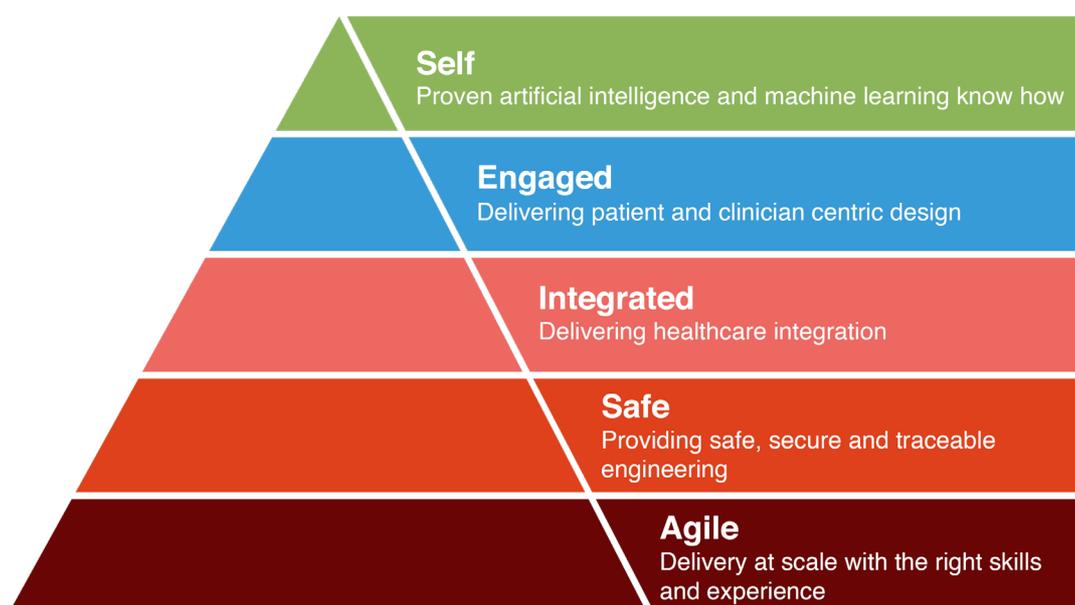


Figure 1. Hierarchy of IT capabilities needed in healthcare

The Mandate for Change

Although the drivers in healthcare for accelerating the adoption of digital technology and for integrating the healthcare ecosystem are well known, it is worth noting how the whole ecosystem is pushing in the same direction. Providers are seeking to improve clinical outcomes with new and increasingly personalized treatments. There is an increase in patient expectations and the need for patient engagement, as well as patient education. In addition, to help mitigate rising costs, payers are increasingly focusing on value-based care.



Figure 2. Drive to Digitalization

At a policy level, regulators see increased patient engagement (both proactive and preventative), delivered digitally, and with new models, as a key policy response to rising costs and rising citizen expectations about their health choices. They are looking to enable and facilitate innovation and investment, and provide data driven solutions controlled by consumers. Regulators see their role to facilitate and not just to “regulate” progress.

Payers (public and private) see new healthcare delivery as a way of controlling healthcare cost inflation and again are driving digital adoption to the market. The focus on value-based care means that clinical decisions need to be efficient and therefore supported by digital tools.

For established providers, their healthcare professionals are burned-out because of the pandemic, and although they seek innovation and investment, it needs to be executed in a way that minimizes any negative impact on staff. Modernizing core EHR solutions is difficult, expensive, and risky; instead, organizations are looking to integrate innovative solutions to their core systems.

New entrants are designing new care models that are predicated on remote and digital delivery, including decision support for clinicians, and patient education and engagement techniques. And in the US, new entrants to the healthcare market are introducing new payment models and technologies to allow patients to manage healthcare costs and payments more easily. These represent significant investments in digital healthcare, whilst accelerating the adoption of it. Rock Health Capital recently reported that US digital health start-ups received nearly \$30bn of funding in 2021, double the level of funding in 2020.

Additionally, traditional retailers are now entering the healthcare market, threatening established players. Amazon has launched Amazon Pharmacy. Best Buy has launched Best Buy Health to leverage its established Geek Squad in home services, as well as offering a more comprehensive suite including, virtual care, home healthcare technology services and senior living services.

Pharma also has an opportunity to reduce costs because of regulatory changes, for example in the way that clinical trials are carried out digitally.

Finally, the COVID-19 pandemic has shown how new digital models can work, overcoming cultural barriers to remote consultations, and leading to regulatory changes. An example of this lies in the US, where cross-border telemedicine licensing was permitted. Digital adoption is happening at pace and scale, for example only 5% of consultations by GPs were remote pre-pandemic, a year later 95% of consultations are remote.

COVID-19 demonstrated the ability of the healthcare system to deliver remote home monitoring at pace and scale, which can increase access to care and decrease healthcare delivery costs. This change delivers real benefit to the patient. However, the basic method of communication between patients and healthcare professionals has not kept pace with this change.

The Voice of the Patient

To understand the need, we must listen to patients. These are three true-life histories that have been anonymized in terms of names and conditions; they show the difficulties that patients and their caregivers face in navigating the healthcare system and show very clearly the need for patients to be connected digitally to their healthcare providers.



01. The Mother Who Cares

When Jane was born her parents were faced with a devastating diagnosis. After many months in intensive care, and many difficult conversations about the future, Jane was sent home just before her first birthday.

Now, at two years of age, she has a plastic tube inserted directly into her neck and is dependent on a breathing machine. Feeds are pumped into a tube in her stomach overnight. The cot her parents bought was replaced by a metal hospital bed that folds down at the side for emergency access, and her collection of stuffed toys has been moved aside to make way for a suction machine and boxes of disposable supplies.

Her mother, Emily, has learned how to be a nurse, as well as a parent. In the first few months after discharge from hospital, Jane had nurses or caregivers coming in every day. Everything was recorded on paper; observation charts, medication charts, daily care plans, emergency care plans, but when the professionals left the paperwork left with them. Now Emily is the only person who knows the full picture. She carries that information in her head and often worries, 'What if something were to happen to me?'

When Jane was unwell with a chest infection and was taken to the emergency room, it was Emily who had to remember all the details about her daughter's past medical history, the result of blood tests and brain scans and her list of medications. She had to repeat the same information six times. Jane is under the care of four different specialist teams at the hospital, which is quite far from home. They hold their outpatient clinics on different days of the week, which means many trips there and back, bringing all of Jane's essential equipment. Emily can see that the doctors and nurses are extremely busy, so she is reluctant to ask all the questions that she has been storing up for weeks. No sooner has she been seen than she is on her way home again. A few weeks later she receives a letter summarizing the findings from the clinic, and this will be stored in a file that she keeps on the hallway table so that, if there is another emergency, she can grab it on the way out.

Children with special health care needs are defined by the U.S. Maternal and Child Health Bureau (MCHB) as “those who have or are at increased risk for a chronic physical, developmental, behavioral, or emotional condition and who also require health and related services of a type or amount beyond that required by children generally.” In 2017-2018, approximately 13.6 million children in the U.S. (18.5%) had a special health care need. One in four households (24.8%) in the U.S. had one or more CSHCN¹.

The families of these children face major barriers in accessing quality health services, including a lack of coordination between services and the sheer complexity of the services they need. The burden of information sharing sits with parents or caregivers at points of handover between departments, teams, or between health, social and education services. COVID-19 demonstrated the ability of the healthcare system to deliver remote home monitoring at pace and scale, but the basic methods of communication between patients and healthcare professionals have not kept pace with this change and rarely involves real-time digital information sharing, or true personalization of care.



02. The Girl Who Waits

Aisha has a rare disease, but she isn't going to let that define who she is. She can't remember a time when she didn't have to deal with hospital visits, x-rays, blood tests and half a dozen bottles of pills on her bedside table. Many of her childhood memories are of the nurses and doctors who cared for her throughout her childhood and

who organized hospital visits to fit around her school exams.

Having her care transferred to adult services was a stressful time. They didn't know her, except for the information they were given on the referral letter, so she had to tell them her whole life story from the beginning. Soon after that she started to ignore hospital appointments and sometimes forgot to take her medication. Nobody seemed to notice.

Then she got sick and had to be admitted to hospital. They said she needed to be assessed for an organ transplant. This had been mentioned in the past, but it still came as a shock. They were not sure whether she would be suitable for a transplant, but they would do a full assessment to find out. That was in April. As she waited for the assessment Aisha continued to see her regular doctors. She met the transplant team for the first time in September.

They went through the same long list of questions and repeated most of the tests. The next meeting with the transplant team was booked for December.

Aisha never made that appointment. She died before the final stage of assessment could be completed.

Her parents raised a formal complaint and that was how they discovered that it had taken over 4 weeks for the referral letter to be written, and another 15 weeks before there was a response to that letter. They uncovered a disjointed, paper-based communication system where there was no oversight of the end-to-end assessment process, and where the impact of staff shortages, periods of leave and limited capacity resulted in patients being 'stacked' in an invisible queue.

When the hospital undertook an audit, they discovered multiple examples of delays due to staff using the wrong form, attaching the form to the wrong patient, and sending the form to the wrong center. There was inconsistency in the way that the referral form was completed, with essential information or tests missing. This meant that appointments had to be rescheduled while the staff contacted the referral center to collect the missing data. Hospital managers reviewed service user feedback from all sources and discovered that waiting was the second most frequent negative comment, after lack of communication and information.

Feedback and explanation are an important component of fairness. If patients must endure waits, they should know why. Moreover, they should agree that the wait is unavoidable and, therefore, that it is reasonable that they should have to wait. If they have a good model for the actions taking place behind the scenes that necessitate the wait, they are apt to accept it as necessary and appropriate.

Digitization of communication and transparency of information sharing opens a process to scrutiny and allows the patient to see 'where they are in the queue'. It gives an opportunity to ask questions and understand delays. Real time communication on a digital platform avoids the loss of data and enables workflow to be managed so that patients are not lost to follow up, at any stage in the care cycle. Digitization can support productivity and efficiency and help solve the problems faced by the workforce in trying to manage a complex cohort of patients on bits of paper and a few spreadsheets.



03. The Man Who Adapts

John was a busy 64-year-old widower, looking forward to retirement, when he started to develop symptoms of fatigue, arm weakness and slurred speech. He had multiple hospital visits and many investigations before he was diagnosed with a neurodegenerative condition.

There was no cure. His family were devastated but John got busy, adapting his home, organizing his daughter's wedding, joining local support groups, fundraising for research, and volunteering to help others newly diagnosed. He researched clinical trials and tried out any piece of technology that would help him retain some independence. He sourced his own equipment from wheelchairs, to ventilators, and eye gaze technology for his computer. As he became weaker and more dependent on others, he started to sort out his affairs, writing an advanced directive and sharing his wishes with his immediate family.

When he could no longer feed himself, he went into the hospital for a gastrostomy. This was not the hospital where his regular team was based and they did not have any access to his medical records, so he had to go through all his medical history, which was exhausting. He was surprised that nobody knew how to operate his wheelchair, or his portable ventilator, and he didn't think to bring the instructions.

At the start of the pandemic John was living on his own, but he needed daily support from a team of caregivers. The impact of staff illness and absence meant that he lost some of his regular team. It was a struggle to train new people in his care needs, especially as he depended upon eye gaze technology to update his own care plans.

When he became unwell one of his new caregivers called an ambulance, even though his advanced directive clearly stated that was against his wishes. Unfortunately, this piece of paper was at his daughter's house. The paramedics waited until she drove there with the document, and he was able to remain at home.

John's multidisciplinary specialist team kept in touch using WhatsApp and then they moved to video consultation, which helped him to keep in touch with those who knew him best. However, it was hard work to prepare for an online meeting, and it could take up to two hours to get through all the questions with his nurse. It would have been useful to be able to have access to an online chat forum where there was less time pressure, or to prepopulate a questionnaire, ahead of the meeting. He is now getting back to a normal routine and is once again engaged with his local support network and sharing his experience with others.

Despite a devastating prognosis John has tapped into a condition-specific community where there is a lot of cutting-edge research, from genomics to therapeutics to AI, and where advances in technology can really make a difference to people's lives, such as eye-gaze communication and voice banking. However, despite being a keen user of technology in every other aspect of his life, he was stuck with a system where clinicians communicate by letter, or even fax. Where he has little option but to repeat information with each 'new' healthcare encounter and where he must take charge of the care process and associated paperwork at home. John was not Generation Z, but he was just as keen to take advantage of the benefits that technology can provide around communication and coordination of care.

The Connected Patient

“The future is already here, it’s just not very evenly distributed” - William Gibson

Since the widespread adoption of broadband internet and smartphones, consumers have daily access to a vast array of advanced technologies in a connected world. Seamlessly tying together our identities as shoppers, parents, and watchers of binge-worthy television shows, we are provided with endless opportunities to state our preferences and get what we want. Order a cab, buy a dress, even get yourself a recreational DNA test and the system will thank you, keep you updated every step of the way, and eagerly ask for your feedback. But when we get sick, we enter a different world. An unconnected world of paper, of unreturned phone calls, of having to repeat your story repeatedly to healthcare providers that speak their own language. It is a world of waiting without information, never being quite sure where you stand in the process, and rarely (if ever) being asked about your preferences or your feedback.

This is beginning to change, however, through the advent of digital health. Spurred by the COVID-19 pandemic and significant amounts of investment and interest from major governments and corporations, innovators have been looking for ways to build a “connected” world for healthcare.

In the unconnected world of today, when someone experiences a new unpleasant symptom like the sudden onset of severe abdominal pain in the middle of the night, they face a series of difficult choices. In the US, for example, their regular primary care provider is closed outside normal business hours, a call to 911 for an ambulance to the ER could end up being catastrophically expensive, and the array of walk-in clinics, urgent care centers, or even pharmacies located inside grocery stores might not have the right level of care. Someone in distress might start putting their symptoms into a search engine like Google or Bing, which was not designed for this purpose and so might lead them down a range of informational rabbit holes that feed their anxiety without providing any relief.

In the connected world of tomorrow (already here for some, though not all), somebody in the same situation might use an AI-backed symptom checker which asks a series of structured questions to drill down on the differential diagnosis. Abdominal pain in the lower right quadrant might have a stronger weighting on a Bayesian algorithm for acute appendicitis, while questions about recent dietary changes might point more towards constipation or food poisoning. Increasingly, such symptom checkers are deployed by insurance companies and health systems to triage their members to the right level of care with the right urgency; importing the patient history into their electronic medical record (EMR) so that healthcare providers can appropriately triage their waiting room and make more efficient use of time. With the right diagnosis and a treatment plan in place, the patient can go home with additional services uploaded to their personal medical record which allows them to better absorb the complex information about what has happened to them in their own time, at their own pace and ideally even in their

own language. Continuous data gathered through wearable devices, patient reported outcome questionnaires, and even the smart speakers in their home can continually monitor the situation and provide a wealth of data at minimal burden to the patient.

Connected Care is changing our Health & Healthcare products



WEARABLES will monitor our oxygen, heart rate, blood pressure or glucose levels in real-time, sending regular updates to both the patient and doctor.



LONGITUDINAL HEALTH RECORDS will be used to better assess the risk of getting an illness and suggesting preventive measures.



MONITORING AND PROACTIVE ALERTING will prompt patients and their carers to check and react to their vitals leading to improved mobility and life expectancy.



IoMT (Internet of Medical Things) will be used to create digital medical twins across entire populations leading to more targeted healthcare products.



ENGAGED CONSUMERS through **POPULATION HEALTH MANAGEMENT** Initiatives will be able to make healthier choices in a value-based care ecosystem.

Figure 3. Different types of connected care

Some people with medical conditions are already living in the connected world; but it's typically those who are wealthiest, most educated, with at least some technical or medical expertise, and often those who are employed in knowledge industries. While the opportunity is there for the connected health model to reduce disparities, whether those be around age, sex, gender, race, education, rurality, first language, or many other variables, there are signs that the early adopters are not necessarily leading to wider gains. Innovative technologies that are only in English, that only work on an iPhone, or that are only available through private insurance companies, for instance, all serve as barriers to those already disenfranchised by a range of barriers to good care.

Navigating the Healthcare Ecosystem

Before we look at the patients' journey, one symptom that is clear from the voice of the patients from whom we have just read, is how disjointed the system really is.

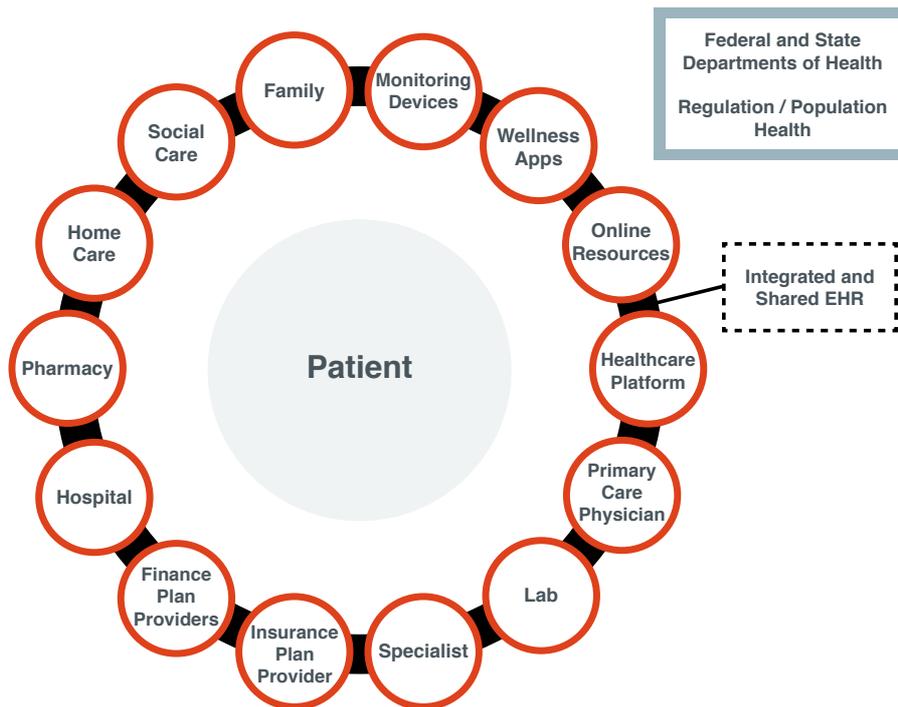


Figure 4. The patients' healthcare world

To address this, the many caregivers, from clinicians, family members, payers, to platforms and technology, must be integrated with a shared health view, centered around the patient. Without this, and as seen in the stories, the patient themselves (or their family) become the care coordinator and the shared health record!

Exposure to the internet, social networks and mobile systems from an early age has created a generation comfortable with cross-referencing multiple sources of information and options while integrating digital, virtual, and offline experiences. And older patients are becoming increasingly comfortable with digital solutions, as we have seen in the patient stories, it is often the older or more vulnerable that can benefit from new technologies.

And from a patient's perspective their health journey should be quite simple: they are well, or they are being treated after their condition has been diagnosed. Patients certainly expect the treatments to potentially be complicated and worrying, but not the administrative pathway.

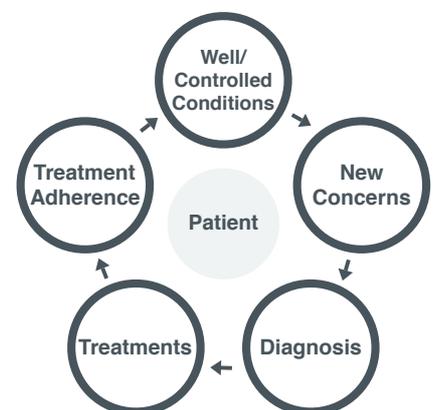


Figure 5. The Health Cycle

Their expectation is to access services at any time and any place, yet the healthcare system continues to pull them into an analogue world. This carries a high risk of disengagement, loss to follow-up and reduced compliance with therapies.

For a connected patient and their clinicians and caregivers, many (and typically most) of the interactions with health providers should be digital.

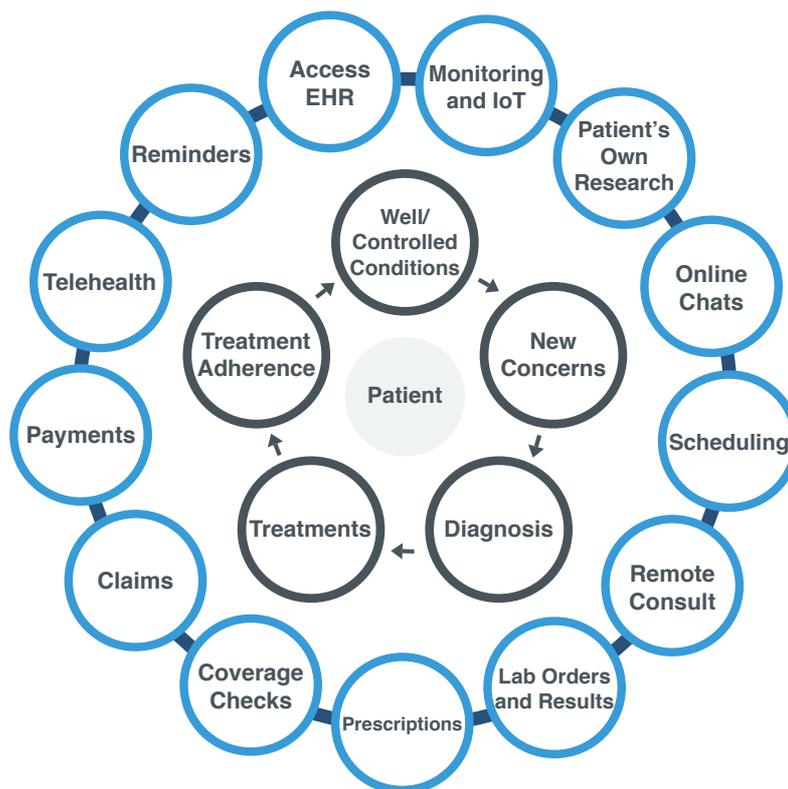


Figure 6. Digital touchpoints along the patient health cycle

The following shows the journey for a patient. They show the patient's and clinician's concerns in the unconnected world, and how these can be addressed by technology for a connected patient.

Experiencing A New Symptom

<p>Patient</p> <ul style="list-style-type: none"> • Need understanding of the potential issue. Googling symptoms, 911, Emergency Room. <p>Clinician</p> <ul style="list-style-type: none"> • Typically, unaware of the patients concerns, can't managing caseload, or manage the information and education of patients. 	<p>Technology</p> <ul style="list-style-type: none"> • Make patients feel connected to the medical team by using app-based reporting systems and confirming to the patient that they have been received. Robust and secure Messaging and Video Call services can do this job, with potential of AI and Decision Support Systems to screen before presentation to medical team.
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Requesting, Booking a Healthcare Encounter

<p>Patient</p> <ul style="list-style-type: none">• Trouble with identifying appropriate urgency, provider, and availability. Having to repeat information to multiple teams. <p>Clinician</p> <ul style="list-style-type: none">• Cannot optimize waiting list management, and workforce scheduling. Does not have full understanding of patient history to manage triage.	<p>Technology</p> <ul style="list-style-type: none">• Building appropriately secure and private interfaces between a consumer facing app and the hospital IT systems is critical. The appliance of AI and Decision Support System can help screen and schedule in a more automated way to ease the scheduling “back-and-forth” and time efficiency considerations on both sides – patient and medical staff.
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Having a Healthcare Encounter

<p>Patient</p> <ul style="list-style-type: none">• Only having a face-to-face option, repeating history, lots of waiting, no visibility over process. <p>Clinician</p> <ul style="list-style-type: none">• Staying current, outcome reporting, communication across organizations, data silos create business challenges, access to the right information in the right place at the right time to ensure right care is delivered, documenting for reimbursement; time involved in manual entry of data for reporting – not continuously collected and displayed data.	<p>Technology</p> <ul style="list-style-type: none">• Portals / Apps and shared record to allow patient and clinicians to understand the situation and share information.• Interfacing complex data back-end systems, with appropriate security and data privacy concerns addressed is a challenge and use up product development team time and energy as the number of disparate systems to be connected continues to grow. It must work for legacy systems and not just modern APIs (Application Programming Interfaces) and cloud-based architectures.
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Getting Tested

<p>Patient</p> <ul style="list-style-type: none">• Difficulty in scheduling, understanding the results, billing implications. <p>Clinician</p> <ul style="list-style-type: none">• Interpreting in context, explaining to patient, responsibility, and accountability, managing large data sets from remote monitoring of patient symptoms and biomarkers, managing patient expectations, risks of diagnostic software and AI bias.	<p>Technology</p> <ul style="list-style-type: none">• Building consumer facing medical devices with the rigor of medical but keep the compliance of commercial apps is critical. UI/UX design experience is needed to navigate these tricky waters. Also, the blending of regulated software medical devices with unregulated platforms is a critical area for consideration, something that both the long-term architecture and the short-term quality processes must consider. This includes change management, post-market surveillance, reporting, traceability, risk management and a host of processes that meet the medical standards, IEC62304, ISO14971 and ISO13485 for Software As A Medical Device (SAMd)
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Receiving a Diagnosis

<p>Patient</p> <ul style="list-style-type: none">• Overwhelmed with information, which is not understood, anxiety. <p>Clinician</p> <ul style="list-style-type: none">• Developing evidence-based care plan, coordination.	<p>Technology</p> <ul style="list-style-type: none">• Expertise in UI/UX is critical to simplify for patients and to provide only pertinent data to the medical teams at the right time.• To develop appropriate clinical software, it is critical to understand the need to have separate controls for software used as a medical device, e.g., involved in the diagnosis, and to have separate controls for software that is the platform to access the data. There must be a clear delineation and supporting organizational approach in technology companies providing the solution.
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Follow Up, Ongoing Management of Condition

<p>Patient</p> <ul style="list-style-type: none">• Not personalized: one size fits all, fixed length outpatient appointments, lack of choice, not human-centric, lack of clarity and transparency about who to call, and when. Does not meet the expectation of access at any time in any place, using smart phone. <p>Clinician</p> <ul style="list-style-type: none">• Clinicians wish to use remote monitoring, video, chat, telephone, triage, multidisciplinary team, making care bespoke to patients. Patient's disease progression is only observed through episodic clinical visits, meaning fluctuations in disease progression are not always captured.	<p>Technology</p> <ul style="list-style-type: none">• Software plays a key role as it can run on the existing patients' phones when they are away from the clinic. This can act as a hub for other devices such as blood pressure, blood sugar or different types of wearables that can connect through the patient phone.• Building the sense of connection through a device that the patient is very familiar with and that is usually with the patient is the key to making the patient feel connected to their medical team. Software design needs to include the requirements related to maintaining compliance and keeping the patient's attention, interest and avoid device and software app burn-out.
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The patient journey should seem simple from the perspective of the patient, but within the overall context of the health system it is complex. Only a digitalized and connected system can give the patient a simple experience.

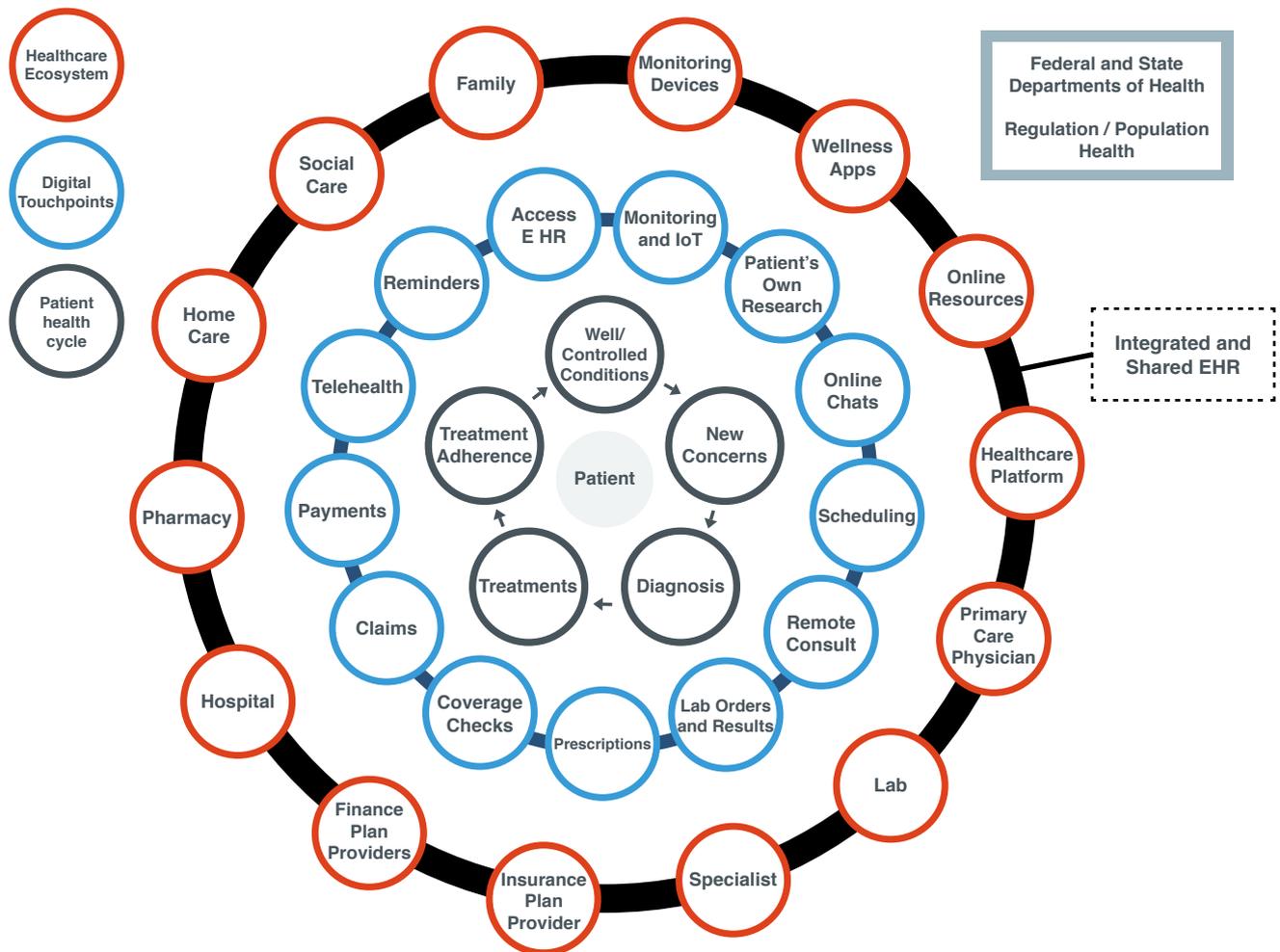


Figure 7. The Health System is complex

Delivering the Promise

Today the technological art of possible is remarkable: wireless networks and sophisticated consumer devices mean that high fidelity communications (video, images, and clinical readings) can be the norm. Cloud vendors provide utility priced compute and storage facilities for the biggest medical datasets, including genomics, and AI and machine learning algorithms provide almost unbounded analysis and engagement possibilities.

The potential and need for rapid digital adoption is obvious, but there are practical considerations around the technical capabilities needed to deliver for the connected patient. These can be placed in a hierarchy of needs, in a pyramid shape, with basic needs at the bottom of the pyramid and more high-level needs at the top (yes, apologies to Maslow!).

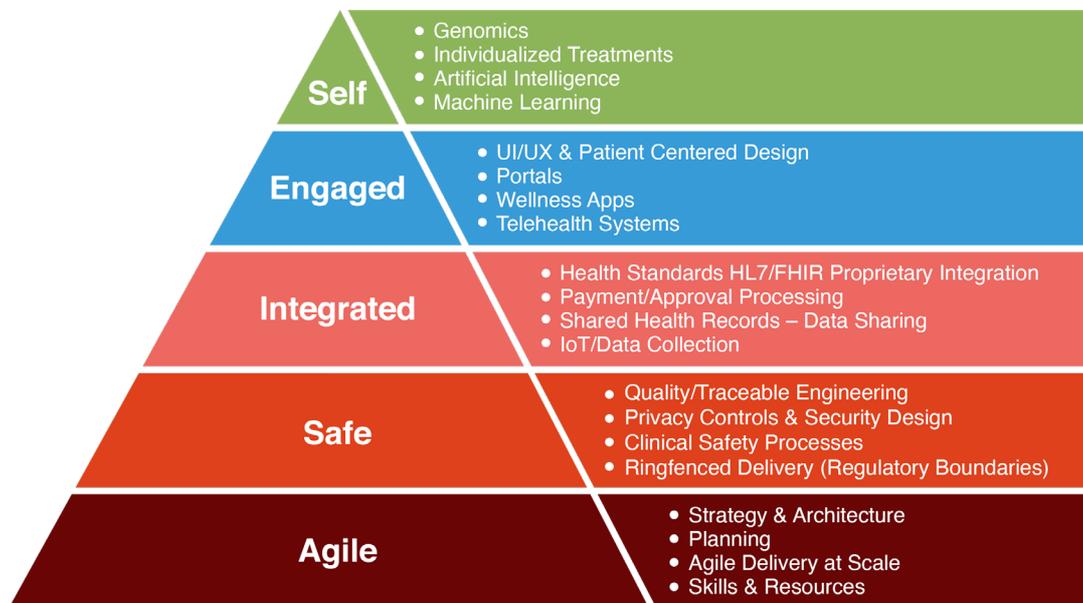
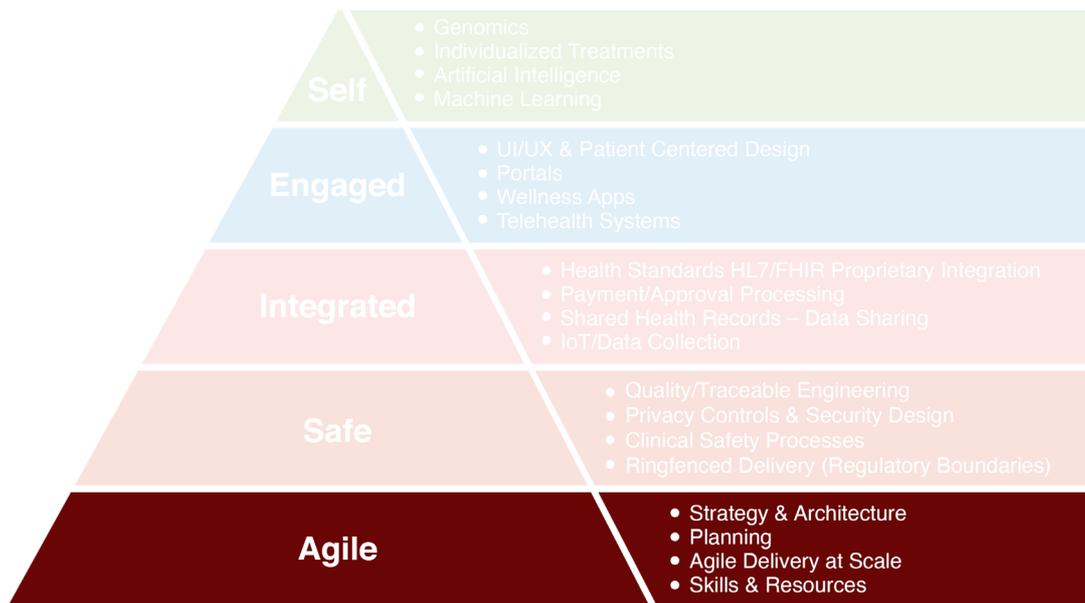


Figure 8. Hierarchy of IT Capabilities needed for Healthcare

Agile

At the base of the pyramid, the industry needs to have access to the right skills; at scale and enabled by effective and agile methodologies. Technologists need to understand and work with healthcare professionals bridging knowledge gaps between the disciplines.

Endava has found that companies of all sizes require this core engineering support.



[We support a digitally powered care provider](#) who is improving the healthcare experience, for seniors, to live more fulfilling lives. For more than a decade, they have been a trusted partner for the nation's top health plans, health systems, and at-risk physician groups navigating the shift from volume to value.

Endava was asked to provide flexible engineering capabilities and resources, including 40 agile software engineers across multiple teams, to meet ongoing development needs for the following: care coordination and discharge processing, online referral management, patient and episode management, integration, and migration.

Even multinationals require support; one of the world's largest and best-known healthcare companies with a global workforce of more than 130,000 people asked Endava to help their software delivery teams deliver more quickly by improving deployment frequency, reducing lead times, and increasing quality. We introduced improved Agile Methodologies including Behavior Driven Development and enhanced test automation, as well as providing flexible team capacity.

Payers also require support; a global health insurance and healthcare group, with over 31 million customers worldwide, asked Endava to partner and provide development expertise because they were not happy with the results from other suppliers. These

capabilities ranged from creative UI/UX expertise, DevOps consultancy through to engineering and testing services. Work covered Quote and Buy, and member and provider engagement.

Endava see a clear trend in the market, digital providers want quality engineering and no longer just have a focus on costs. There is also often a tendency to focus on the technology itself, even though its effectiveness will depend on the skills, behaviors, and organizational cultures of those developing it and using it. At a planning and strategy level access to healthcare, specialists and leaders will help assure success.

Patient-centric organizations benefit from digital transformations; one of the UK's leading cancer charities, who has been helping people living with cancer for over one hundred years, understood that the way they work has had to change over time, to ensure they are offering the right support, tools, and inspiration. To make this a reality, they needed their technology to be fit for the future, too. It was time for a digital transformation.

[Endava was engaged](#) to collaborate and create a technology roadmap aligned to the charity's target operating model and business strategy. Endava was trusted to develop the roadmap which will guide a three-year transformation program, and which will represent a significant investment in technology for the charity.

Healthcare is complicated and requires a long term relationship with a deep understanding of the required engineering processes and the quality system, and a commitment to deliver however difficult the challenges the project may have.

Medical device manufacturers benefit from test automation and continuous integration; for over 20 years Endava has been a partner, delivering several software projects, to a leader in the life sciences, diagnostics, and applied chemicals market. The company provides laboratories worldwide with instruments, services, consumables, applications, and expertise.

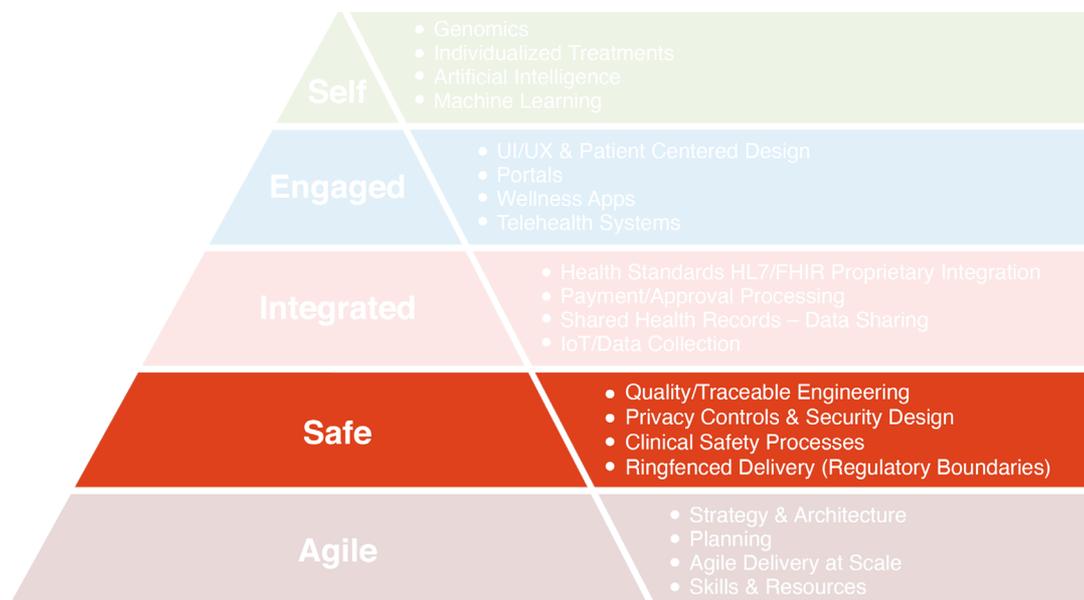
One solution developed by Endava provides automated and remote pharmaceutical Operational Qualification (needed when there have been any software upgrades at a client site). The solution replaces several hours of onsite testing by an engineer with 15 minutes of remote automated testing.

The client had very specific demands with regards to the software development life cycle. A continuous integration process was established for all products; builds are automated and inter-dependencies automatically managed for all applications in the product portfolio, including the execution of unit tests and the calculation of the code coverage for each build. This takes a long-term approach to engineering and partnership.

Safe

The next layer of need in the pyramid covers safety. Developing for healthcare, as is the case for other safety and critical infrastructure, requires quality processes and traceability through the product's lifecycle.

In the fast-paced environment of digital products, bringing new features to customers and adapting quickly to market changes is a key business differentiator. Our Continuous Delivery engineering practices streamline the idea-to-production cycle in a safe, fast, reliable, and repeatable manner. We build security thinking into our software development lifecycle by investing in our people, tools, and processes, so that these systems are secure by design.



For example to show the typical capabilities needed in healthcare software development, Endava was asked to help a leading healthtech company with the development of a mobile, cartridge-based, critical care IVD Point-of-Care medical device (a blood gas analyzer). The main capabilities of the system included real-time monitoring of all connected blood gas analyzers in the hospital, validation workflow of patient and QC data, POCT1a, ASTM and HL7 connectivity, all with extensive reporting. The Endava team helped the development of the firmware, connectivity, backend, and frontend applications; always working in compliance with ISO 13485, IEC 62304, and ISO 14971 to meet the US and EU medical device regulation, and to standards defined by ASTM, POCT1-A2, and HL7.

Moreover, software in the medical world has higher standards of compliance than in most other industries, and therefore is costly and takes longer to develop and change.

As with all clinical devices or treatments, any adverse effects on patients caused by the software needs to be traced through to the relevant design decisions, and any remedial changes need to be fully impact-assessed before implementation. In addition, changes to medical device software must be assessed in terms of its impact on the patients' risk/benefit ratio. This means that changes and decisions must be fully traceable.

At the heart of any management approach for “Software as A Medical Device (SAMMD)” is the concept of identifying which parts of a solution is the Medical Device and which parts are other non-medical components – ringfencing the higher compliance components.

The overall approach needs to cover all stages:

1. Planning & Strategy
 - Identification of standards
 - Training and education of issues related to medical software development
2. Requirements & Design
 - Traceability
 - Change Management
 - Post-market safety monitoring
 - Incident reporting – leading to risk re-assessment
3. Construction & Verification
 - Traceability
 - How any “Medical Device” codebase will be isolated from other modules
 - Design documentation
 - Technical dossier for 501(k) / MDR
4. Testing, QA, and Validation

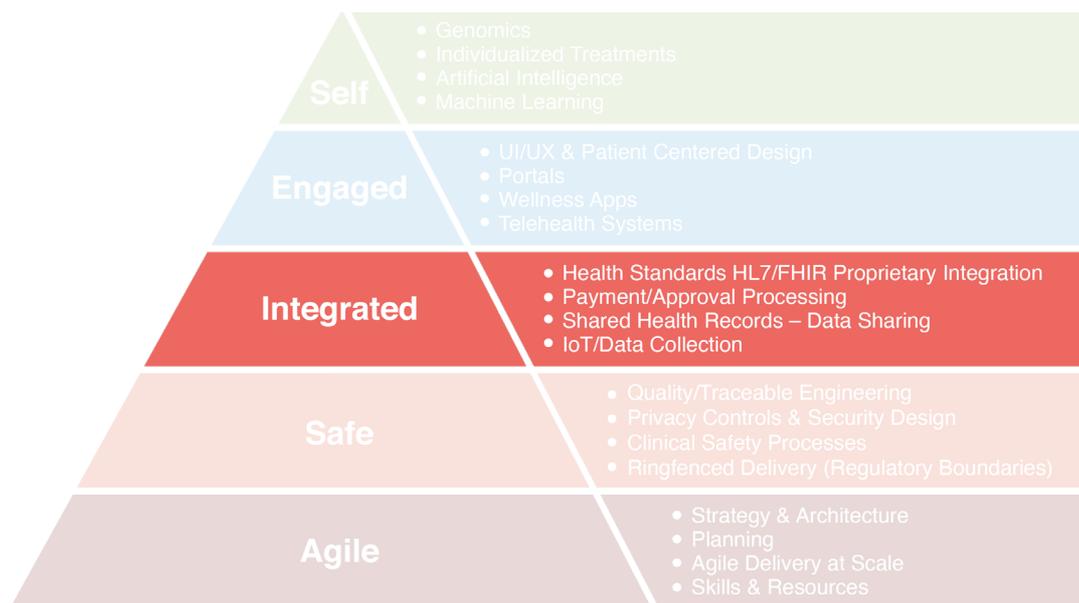
Both established players and start-ups require the same compliance capabilities.

One of our established clients has over 230 years of industry experience and is one of Ireland’s leading scientific solutions providers offering complete application solutions to Scientific, Medical, Industrial, Academic and Food Science markets. Endava provided them with complete product development lifecycle services from architecture, UX, implementation and validation to production, working within healthcare regulatory compliance (FDA CFR 21, Data Integrity, ISO 17025).

A new German healthcare company founded in 2010 from a university clinic, whose long-term goal is the development and establishment of improved therapies for the resuscitation of patients with cardiovascular arrest, asked Endava to provide the engineering capacity and know-how for the required embedded software development for their new medical devices. Functional safety and security needed to be addressed throughout the product development cycle, including compliance with ISO 13485, IEC 62304, and ISO 14971 to meet the US and EU medical device regulations. Endava ensured traceability from requirements down to single source code commit, as well as across tests, risks, and change requests.

Integrated

Integration and integrated health are the next layer of need in our pyramid. Integrated care paths and integrating systems has been a major challenge and undertaking in healthcare for many years. The HL7 (and now work on FHIR) have developed to meet much of the traditional health delivery models, for example order and results lab integration in hospitals.



Endava both uses and helps provide healthcare integration tools. One of our long-term partners has been involved in FHIR since the beginning of the standard and are continuously contributing to it. They are the driving force behind FHIR DevDays and a founding member of the FHIR Business Alliance. They provide essential FHIR software and tools for healthcare providers, health IT vendors, consulting firms, and national health authorities. Endava, through our long-term partnership, provided and managed the software engineering teams who created many of these tools.

However, some new scenarios require proprietary integration while standards “catchup” – for example providing payers access to parts of a patient’s health record to support value-based care.

[Endava worked with a US based healthcare provider](#) who has the vision of empowering users to take control of their wellbeing. Subscribers can personalize their experience by importing data captured through their smart wearables and combining it with anecdotal measurements of things like stress levels, medication usage and test results. With so many different apps and devices out there, a unified, technology agnostic experience was essential.

Endava designed the platform so that it can seamlessly integrate with each corporate customer’s brand, creating a community feel and allowing rewards to be allocated to exercise or nutrition-based challenges that keep users engaged.

With 100,000 plus users providing real-time data, there is a lot of insight to be gained about the wellbeing of users. But data is only as good as its source and the strategy behind it. Endava worked to fully understand where the value lay in the data, and how to integrate various APIs to aggregate and consolidate it while providing an attractive and intuitive user interface to make the most of it.

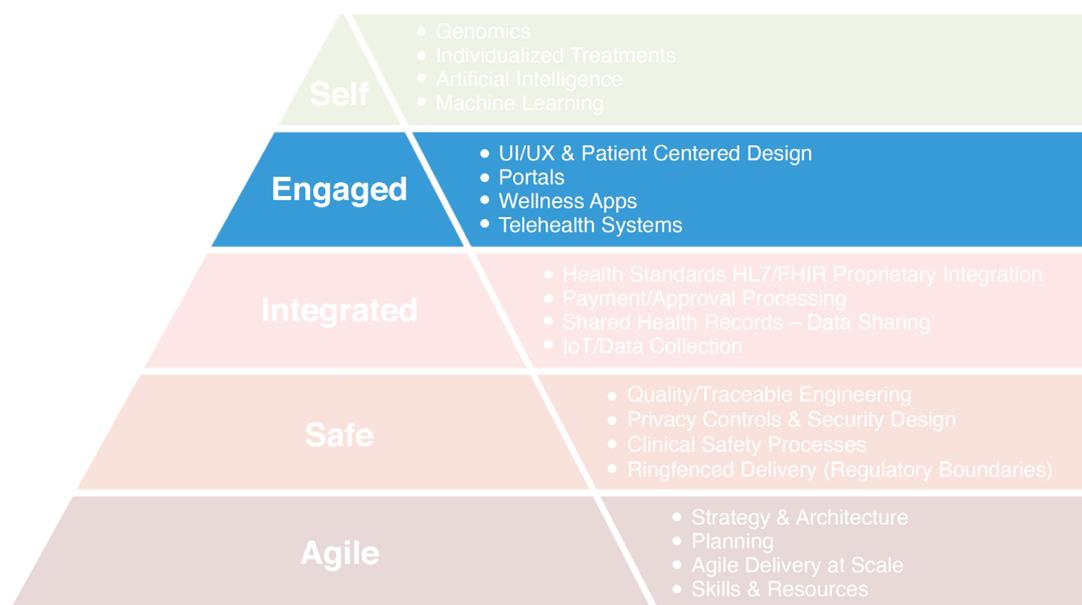
Integration should happen at three levels: Management Layer, Data Layer and increasingly a real-time Control Layer. These three fundamental systems engineering layers should be independent of each other, so that when Management Systems break down, at least the data is still being collected. When the Data Layer may not be working, the Management Layer can still operate and report on the Data Layer.

Many of these issues have been solved in other industries such as Telecommunications, Banking, Large-scale Cloud systems and others. Lessons can be learned and then combined with the regulatory context of the healthcare industry to apply the right solution.

For example, Endava brings a wealth of practical experience and know-how from the high security and high-volume payments industry, not least from our long term strategic partnership with WorldPay, a leading digital payments provider.

Engaged

The next layer in the hierarchy of needs is Engagement. Engaged and connected patients, managing their health better and understanding how to navigate the health system leads to improved clinical outcomes while managing cost inflation. This includes education and adherence to wellness and treatment plans.



Of course, resolving this requires special expertise in user-centered design, but it also requires the engineering capability to produce a scalable solution helping millions of users for little marginal cost.

We deliver the right user experience design through continuous user research, interviews, prototyping, testing, and iteration to understand and empathize with users. A US national trade association, representing almost 80 non-profit health plans, set out to find a clinical solution to help with mental health. Research has confirmed that individuals can leverage neuroplasticity to rewire pathways in the brain. Simply put: we can train our brain, like our body, to handle life's daily stress.

The association selected Endava to help create an app that is a private, user-friendly digital life coach that helps users navigate through life's toughest moments and build the resilience necessary to thrive.

In Europe, Endava developed IRIS, a powerful and reliable national scale primary healthcare solution, in cooperation with the Association of Health Institutions of Slovenia. Major primary healthcare providers in Slovenia have used the IRIS system as their core system for over a decade.

Technology is breaking down the traditional barriers of monitoring and delivering care. Remote monitoring of patients outside of conventional clinical settings, e.g., in the home, may increase access to care and decrease healthcare delivery costs.

In chronic disease management, technology can significantly improve an individual's quality of life and provide independence, prevent complications, and minimize personal costs, with services integrated around the patient and to reduce the number of hospital admissions.

For example, a US based client [launched its telehealth solution](#) as a way for healthcare organizations to provide continuity of care, increase engagement, and deepen connection with patients. As part of an integrated platform, the solution allows providers to share prescribed exercises and education with patients in real time and track and monitor patient recovery and adherence.

They chose to partner with Endava to develop an immersive media telehealth experience based on our engineering expertise, ability to scale and our successful model of working with blended teams.

Thanks to Endava's immersive media overlay, a basic telehealth appointment can become a precise consultation where range of motion can be measured, images and data securely captured, and progress measured thanks to a combination of machine learning and artificial intelligence. There are no complicated devices that need to be purchased; all you need is a smartphone, tablet, or laptop with a camera.

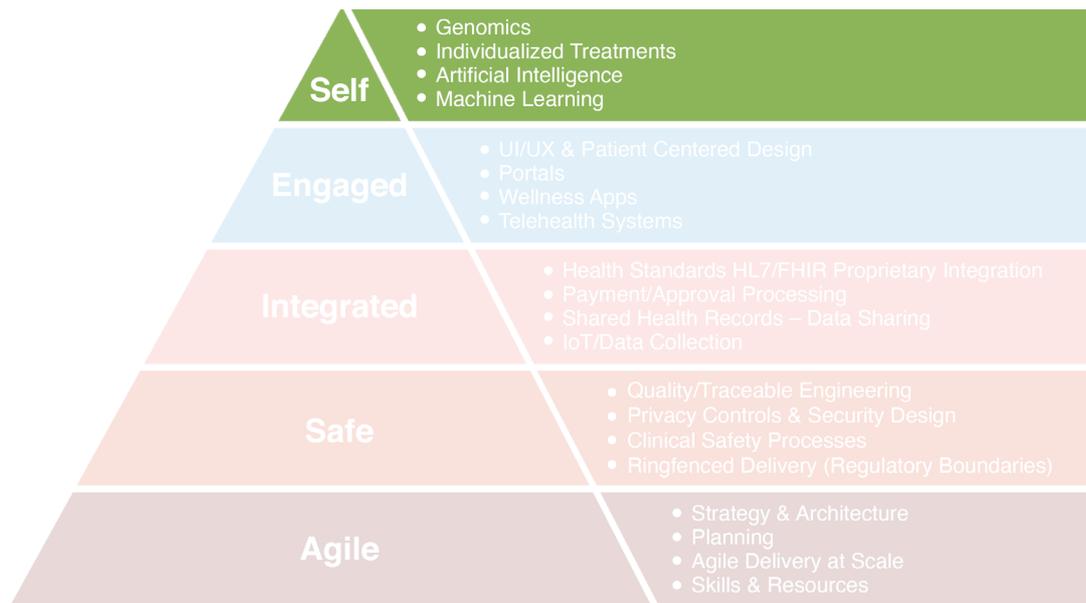
Finally, healthcare systems for patients need to be designed to address the users' special needs. Different devices can be targeted at children, young adults, the cognitively impaired, and those with other accessibility issues.

Endava worked with a technology company that consists of physicians, software engineers, mathematicians, web developers, graphic designers, 3D designers and 3D animators with a zeal to create world-class software solutions for the field of Dermatology.

Endava was engaged to develop the iPad EHR product which features a unique UI and detailed 3D anatomical map of the human body where patients can document their symptoms. It is a fully certified, HIPAA compliant system that supports ICD coding and billing.

Self

Finally, we come to the highest level. This is where we aim to create a personalized experience for a connected patient. A patient receiving individualized care, perhaps based on genomic information, but also based on AI supported analysis of the patient's specific circumstances.



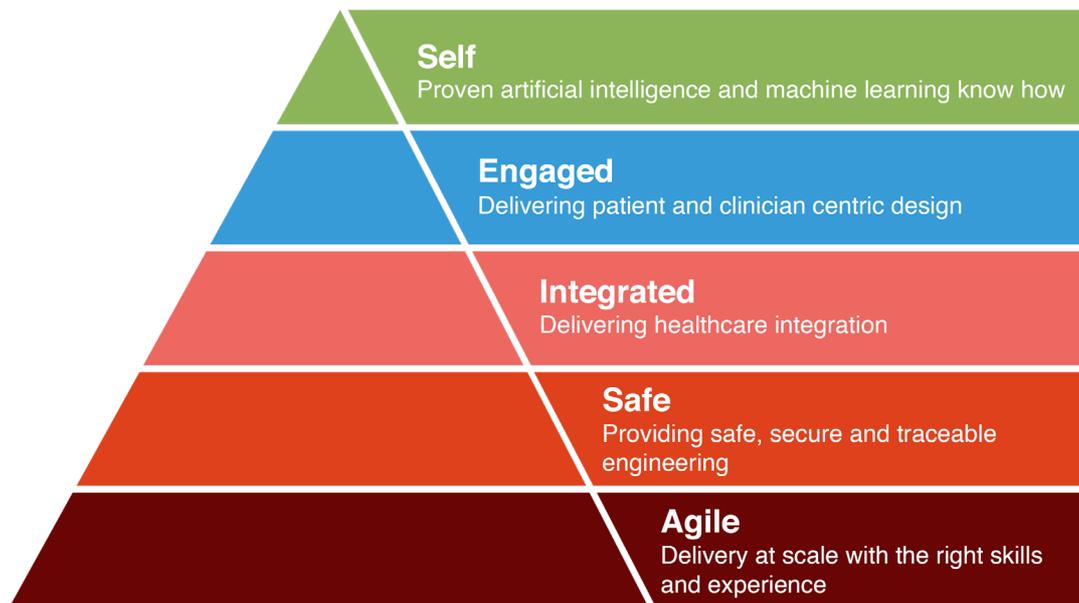
Endava's past projects at this level have included classifying documents for business process management, retrieving information from complex documents, forecasting risk, recommending tasks using written visit reports in healthcare, and classifying emails for support chatbots.

For example, this brings us right back to [our client the digitally powered care provider](#) we mentioned earlier at the foundation of the pyramid, who is improving the healthcare experience for seniors to live more fulfilling lives. Powered by a predictive technology and decision support platform that provides clinicians and care teams with evidence-based protocols, their smart-touch, proven care model fully supports patients from pre-acute to the home. Patients can enjoy more days at home, and healthcare providers and health plans can significantly reduce costs specific to unnecessary care and readmissions

Technology can also save clinicians time, increasing efficiency, reducing delays and costs.

We support an international and leading technology enterprise operating in the fields of optics and optoelectronics. They chose to partner with Endava to develop a solution which provides an easy way to analyze and segment microscopy images. This allows users to analyze thousands of cells a day through automated image analysis and save hundreds of hours of time. The solution brings state of the art deep learning algorithms for image segmentation. By partnering with Endava they were able to leverage our technology expertise and capacity, as well as ensuring knowledge retention.

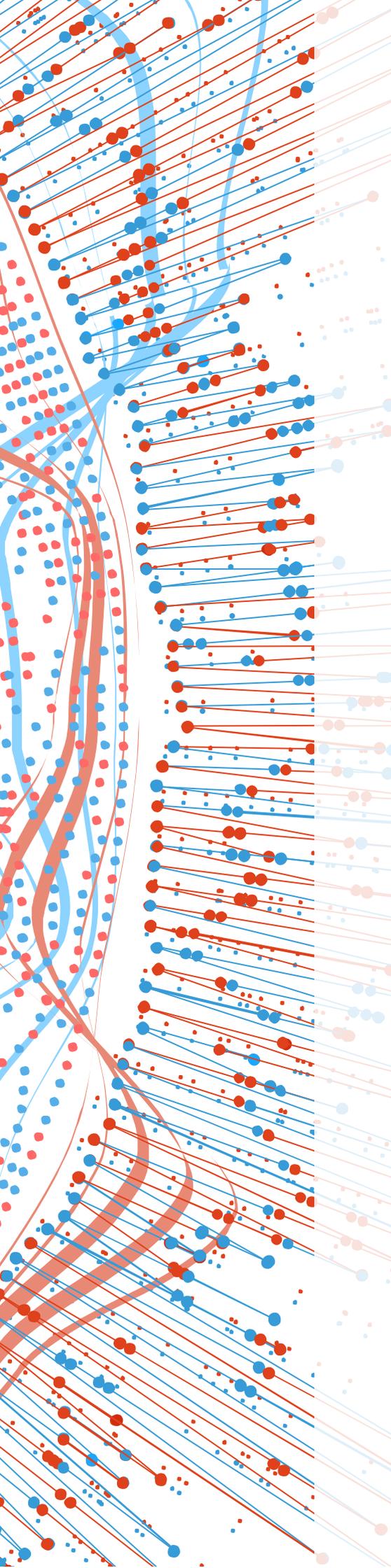
Conclusion



Our aim is to help our partners ensure that care can be delivered digitally and where possible at the patient's convenience, and with treatment that the patient understands and therefore is motivated to adhere to. Supported by a team who has the right context at their fingertips, and who are alerted at the right time to intervene effectively.

We help our partners deliver digital healthcare for the connected patient.

¹ Children with Special Health Care Needs: NSCH Data Brief, July 2020. HRSA Maternal & Child Health Bureau, July 2020, <https://mchb.hrsa.gov/sites/default/files/mchb/programs-impact/nsch-cshcn-data-brief.pdf>. Accessed February 1, 2022.



About Endava

Company Overview

We accelerate our clients' ability to take advantage of new business models and market opportunities by ideating and delivering dynamic platforms and intelligent digital experiences that fuel the rapid, ongoing transformation of their businesses.

By leveraging next-generation technologies, our agile, multi-disciplinary teams provide a combination of Product & Technology Strategies, Intelligent Experiences, and World Class Engineering to help our clients become more engaging, responsive, and efficient.

Learn more at endava.com

Our Technology Advisory Community

This paper was authored by Endava's healthcare industry team with expert and passionate contributions from the below members of our Technology Advisory Community (TAC), providing both clinical and health technology insights. We are proud to add voice, advocating for the need for connected patients.

John Dunne, PhD, has over 25 years' broad technology and commercial experience as a technology entrepreneur, starting, growing and operating technology companies, and serving on the board. He was a finalist in the Entrepreneur of the Year competition in Ireland and received the Irish Times Innovation Award for a telecoms system innovation.

Dr. Gillian Halley has over 20 years' experience as a medical consultant in frontline healthcare delivery, with 5 years as service director, is a recognized NHS innovator in transformational change through digital health technology, and has been awarded innovation funding from the NHS, Innovate UK and SIBG.

Paul Wicks, PhD, has over 20 years' experience in digital health and clinical research, specializing in scientific evidence generation, commercial business models and patient-generated health data.