

White Paper

Switching On the Lights

Benchmarking digital health systems across EMEA

AURELIO ARIAS, ENGAGEMENT MANAGER, EMEA THOUGHT LEADERSHIP, IQVIA

AARON WRIGHT, ANALYST, EMEA THOUGHT LEADERSHIP, IQVIA

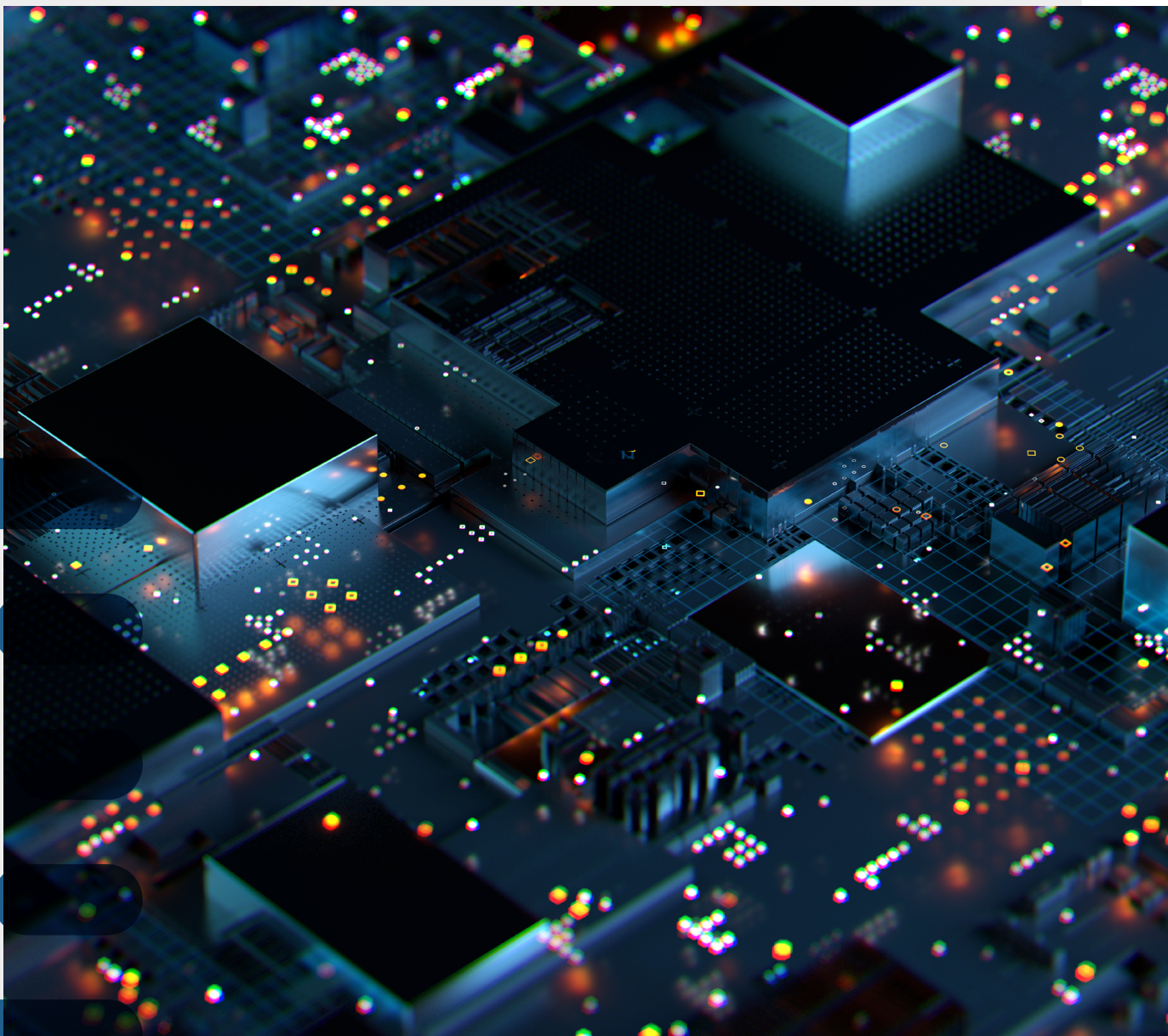


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Introduction

The role of digital technologies in health systems has deep roots: from the early development of structured medical records through to telemedicine, which prepared the world for the remote delivery of care which was so vital during the COVID-19 pandemic. In addition, the variety of communication channels made possible by the internet has created the reality of today's multi-channel engagement between pharmaceutical companies and healthcare professionals.

As the digital technologies which are embedded into our lives were invented, their role in healthcare has been rapidly explored, paving the path towards greater integration. However, that does not mean that the adoption of digital technologies has been uniform across countries. In fact, there is a broad spectrum of difference between even the most sophisticated systems. For pharmaceutical companies, understanding a health system's digital maturity is crucial for effective engagement with its various stakeholders.

In this paper we examine the state of digital health across EMEA. We use a maturity framework that takes into account the wide-ranging nature of health systems, from a country's Initiatives through to its Infrastructure and Implementation. We have surveyed IQVIA experts to assign maturity scores to countries so they can be compared quantitatively, allowing us to highlight general trends between them.

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The evolving health system

Health systems have undergone digital transformation through marked shifts in technological advancements. It all began with the advent of the first electronic medical record in the late 1960s¹ that turned a loose collection of illegible hand-written notes into an organised system, allowing physicians to see patterns and draw conclusions between discrete medical conditions. Since then, the arrival of personal computers in the 1990s allowed clinics and hospitals to capture data at scale. The internet in the 2000s enabled transmission of this data across different care settings (e.g. hospitals and GPs). The 2010s saw regional integration of Electronic Health Records (EHRs) and the 2020s will likely see connected data sets from multiple sources at a national level and widespread use of this network to inform clinical and policy decisions.

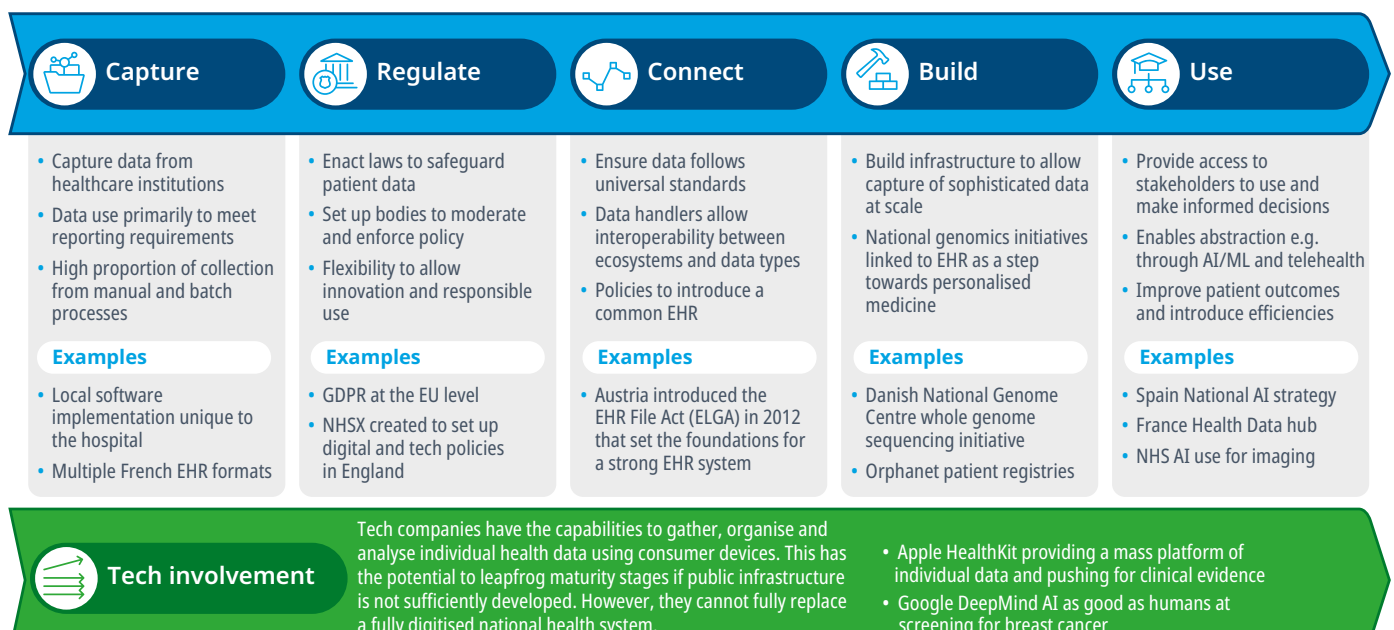
Nations broadly follow a similar path towards digital maturity, beginning with unstructured data capture and progressing towards connected databases that facilitate advanced analytics (see Figure 1). This evolution requires significant public investment and regulatory support to connect the multitude of systems in use. Additionally, private ventures play an important part in developing solutions for each stakeholder, with none more impactful than those originating from the tech sector where the most

promising innovations lie in adapting mass-market consumer devices to capture health metrics with medical-grade sensors.

More recently, the COVID-19 pandemic prompted governments to impose unprecedented social and economic restrictions across large parts of the population and industry respectively. Tackling the pandemic has been facilitated by key attributes of a connected health system, namely widescale data gathering, global collaboration and rapid insights. In addition, telehealth allowed care provision to continue remotely with the added benefit of increasing hospital capacity for emergency visits.

The increased burden on health systems, on top of the limited resources they possess, makes continued digital expansion an attractive proposition to generate savings by driving large efficiencies at scale. However, the real excitement comes from the promise to provide superior population health management from better data and deeper insight, for example by improving patient outcomes and avoiding later complications.

Figure 1: The digital evolution of health systems



Benchmark study results

OVERALL SCORES

The summarised results from the Digital Health System Maturity Score are the average of all scores from twelve elements, detailed in the Methodology section of this paper. The scoring corresponds to discrete stages in a country's path towards maturity:

1. Very little digital progress
2. Underdeveloped and challenged
3. Developing rapidly with potential
4. Regional maturity and scaling
5. Sophisticated at a national scale

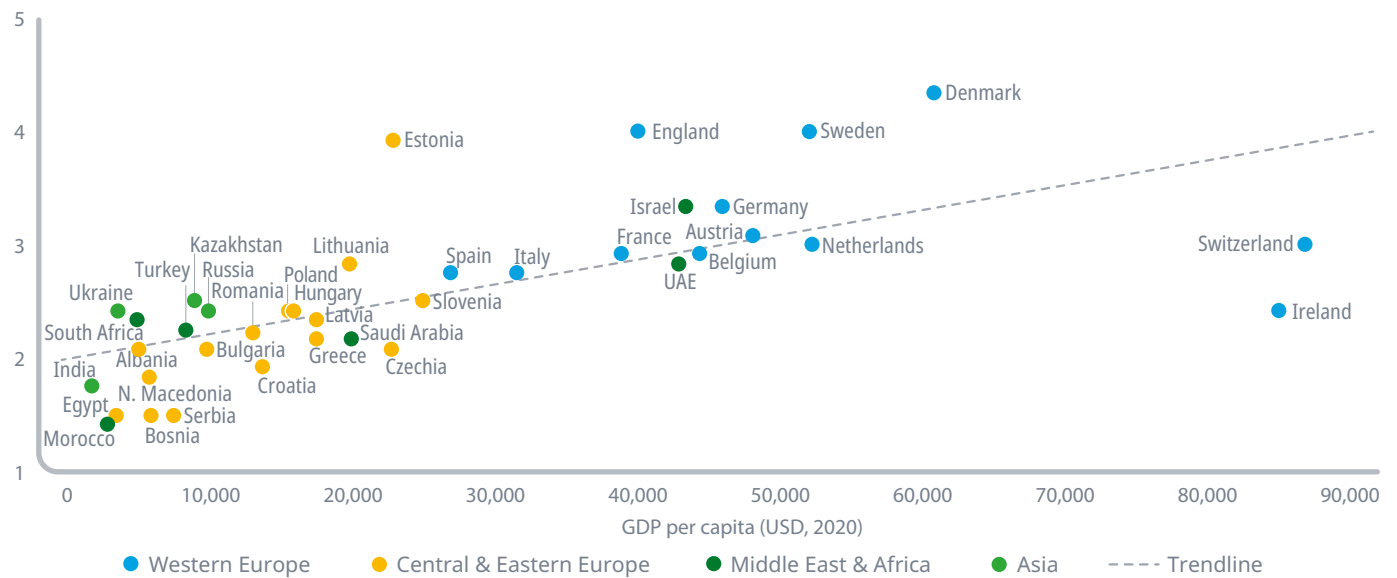
As demonstrated in Figure 2, there is a strong positive correlation between the Maturity Score and GDP per capita, implying that richer nations score higher due to the resources at their disposal. Large scale digitisation requires strong cultural, political, economic and regulatory environments to establish well-funded and trusted frameworks. Additionally, competency in implementation relies on a large and skilled labour pool driven by singular vision.

The correlation against absolute GDP is weak (not shown) which suggests that maturity is more common in small wealthy nations as opposed to ones with a large population base and lower GDP per capita. This is likely due to smaller countries having a simpler path to digitising a few key hospitals that serve the majority of patients, a homogenous population that have similar cultural attitudes towards sharing health data, and political centralisation around capital cities allowing for strong decision-making power.

Estonia, England, Sweden and Denmark are the largest positive outliers. The elements that have set them apart are wide-scale national genomic programmes, advances in decentralised trials and the use of national health data to make evidence-backed decisions. Factors that have allowed them to outperform their peers include a:

- Long history of attempting to digitise their health system as highlighted by Estonia
- Highly centralised health system like NHS England
- Cultural disposition towards ambitious projects such as whole genome sequencing at a national scale such as seen in Denmark.

Figure 2: Digital Health System Maturity Scores



Digital Health System Maturity Score
 A country's overall rating is constructed from 12 elements and scored against peers from 1 to 5

- 5 – Sophisticated at a national scale
- 4 – Regional maturity and scaling
- 3 – Developing rapidly with potential
- 2 – Underdeveloped and challenged
- 1 – Very little digital progress

On the other hand the highest GDP per capita nations, Switzerland and Ireland, are among the largest negative outliers. The reason for the lower-than-expected scores for these two countries are the low use of EHRs in Ireland and the underdeveloped EHR network in Switzerland. Neither country has rolled out state-of-the-art projects such as the whole genome sequencing of large parts of their population, use of artificial intelligence at a national level or running virtual studies.

Very few countries break past a score of 3.0 which indicates EMEA is on average mature at a local or regional level for most elements in the study. All Asian and Central & Eastern European countries except for Estonia are in this bracket but show a wide range between 1.5 and 3.0. There is much that can be improved in these countries and the pitfalls and triumphs from peers can serve as templates from which they can progress rapidly. For example, Slovenia has an e-prescription and e-referral system in place and Lithuania has a functioning EHR network with additional plans to improve its scope in its Action plan of eHealth System Development Programme 2018-2025.²

Developing economies tend to have lower scores on aggregate, mostly remaining under a Maturity Score of 2.5, indicating that on average they are advancing at a local level but find scaling to regional and national levels challenging. However, in this study there is little resolution between them as most are working to build out their infrastructure and the small differences in

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their maturity are not captured. Further investigation needs to be done to cater for the unique solutions in these countries, such as the leapfrogging of landline services directly to mobile.

INITIATIVES, INFRASTRUCTURE AND IMPLEMENTATION

As defined by the framework (see Methodology section), the 12 scored elements are grouped into three categories:

- **Initiatives** (Policy, Funding, Data Governance, Institutions) measures the foundations from which a country can begin its digital journey
- **Infrastructure** (Electronic Health Records, Data Standards, Omics, Interoperability) examines a country's ability to take elements from Initiatives and create a backbone of interconnected systems and high-grade data
- **Implementations** (Telehealth, Artificial Intelligence, Information use, Virtual Studies) captures a country's ability to abstract the data to make a real impact in population health management

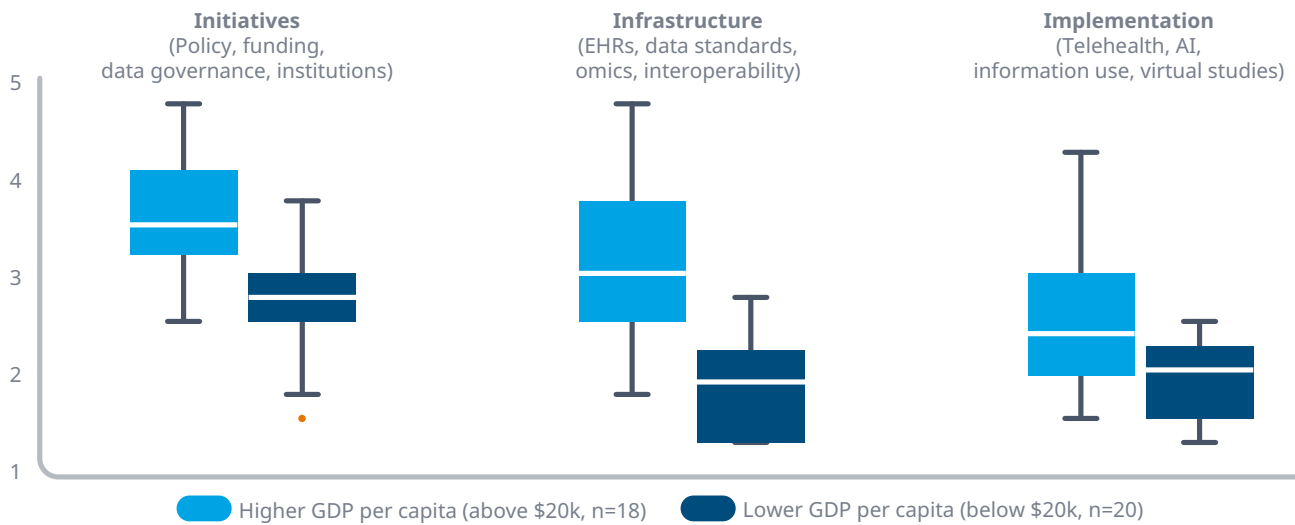
When Initiatives, Infrastructure and Implementation are compared within the whole dataset, there are some clear trends that can be seen between countries of higher and lower wealth bands (Figure 3).

At a high level the countries follow a waterfall pattern with maturity scores descending from Initiatives to Implementation as we would expect from a natural progression towards maturity.

Higher GDP per capita countries show a greater score on average across all metrics than lower GDP per capita countries, emphasising the primary importance of a well-resourced population in driving digital maturity. They have the financial resource, legal structures and social willingness to invest in greater digital integration.

For higher GDP per capita countries the data shows a tighter min/max range for Initiatives than for Infrastructure, alluding to the fact that most have policies and frameworks in place but vary widely in

Figure 3: EMEA Digital Maturity Scores across Initiatives, Infrastructure and Implementation



their ability to translate these into capable systems that would carry them out. Having said that, the interquartile ranges for this cohort across all three categories are of similar magnitude, demonstrating a level of consistency across these countries.

Building out infrastructure is hard and most developing nations have struggled to make headway at a national level. Lower GDP per capita countries have a narrow interquartile range at the Initiatives level, showing remarkable regularity in furthering their digital ambitions, but it widens when it comes to Infrastructure as they too struggle converting policy into action.

Interestingly, lower GDP per capita countries have a tighter interquartile range and a higher median for Implementation than Infrastructure. This shows that with a lack of appropriate public support, poorer nations will meet demand for digital services through the private sector or localised initiatives. These may come from a resourceful hospital, a large tech-hub or an enterprising mobile phone carrier that expands into telehealth. However, there is a limit to this growth as they are often stymied by the lack of national infrastructure that only a government would have the mandate to implement and struggle to scale to a national level.

Across Infrastructure and Implementation, higher GDP per capita countries tend to have a wider spread of scores that overlap with those of lower GDP per capita countries demonstrating that a country's wealth is not the only determinant to digital maturity. Other factors include:

- **Centralisation of power:** In some countries, like Switzerland, Germany and Spain, the autonomous regions or states are highly influential. This may impede their ability to form a consensus on setting standards, allocating funds and choosing vendors. Contrast that with centralised nations like Lithuania or Denmark that can form singular directives and drive effective standardisation and interoperability.
- **Social acceptance:** Countries that trust their institutions and the sharing of personal health data for good causes allow for complex projects to take place. In the Nordics and Estonia, the general population see greater value in sharing their data and do so with little pushback. However, not all countries have the social and political culture to do this, rather they put greater emphasis on data privacy and can have strong reactionist values. England in 2021 had to stop a programme to put GP records in the cloud through its *Care.data* programme and Germany has introduced laws stating that patients will have to voluntarily opt-in to uploading their health data, a move seen as hampering the adoption of EHRs.

- **Experience:** The time since the first national digital policy can lead to clues to identify early digital adopters who have since had the chance to correct any mistakes made along the way. Israel, England and Estonia are countries that have a long history in digitising their economies and paved the way for others. Germany is a country that has only recently revamped its digital health strategy to accelerate its path towards maturity but has found that navigating the complexity of its health system is a huge and time-consuming challenge.

Figure 4 shows the year select policies were first introduced and the weak trend between year of introduction and maturity score. This chart demonstrates the wide variety of approaches in establishing policies by different countries in EMEA across the past couple of decades and the higher proportion of dedicated laws on Digital Health and EHRs being passed in recent years.

DEFINING ARCHETYPES

Countries can be classified into three archetypes depending on their state of digital maturity. Figure 5 shows countries scoring highly in combinations of Initiatives, Infrastructure or Implementation (see the 'Methodology' section for definitions). Scores over 3 are considered 'high' and those that are equal to 3 or below are 'low'.

The archetypes are split out into three groups:

- **Architects** are countries that have a high score in Initiatives. They have strong policies, funding, data governance and institutions. They are a varied mix, but typically have launched ambitious digital health laws that are well-funded but are yet to build out compliant infrastructure. The UAE and Lithuania for example hold strong data governance principles and Spain and Italy have comprehensive laws but are challenged by uneven implementation at regional levels.

Figure 4: Introduction of notable digital health policies

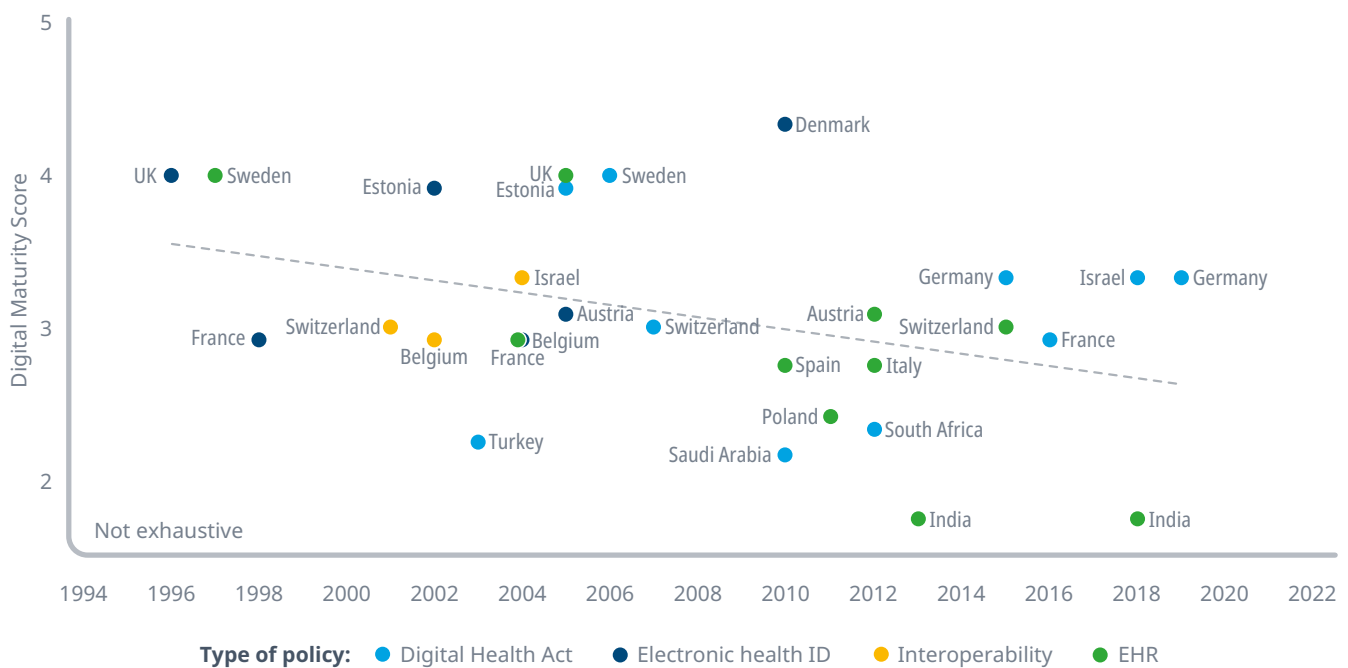
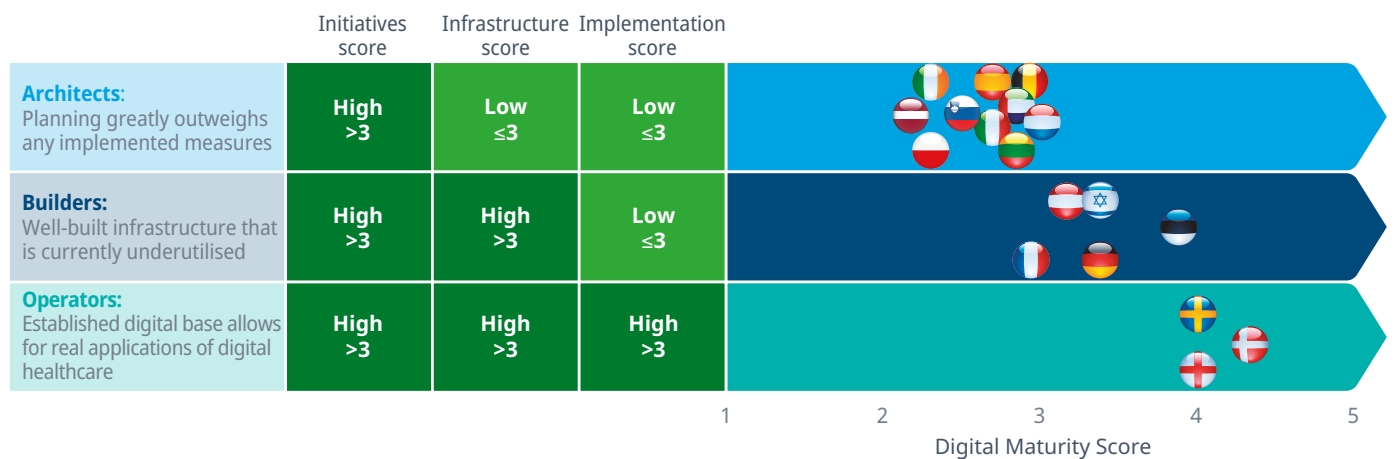


Figure 5: Digital maturity archetypes



- Builders** are countries that have significant initiatives in place and a high degree of developed infrastructure such as France and Germany. Builders have comprehensive digital laws and their infrastructure is largely in place, but they are lacking the incentives or legal structures to make use of this data at a national level such as with Austria. Other examples include Estonia which has successfully built digital health services around its e-ID introduced in 2002 and Israel introduced a law in 2004 forcing all sick funds to be paperless - in essence driving digital adoption early on.
- Operators** are countries higher up the maturity curve that can leverage the digitally connected infrastructure they have created. Operators generate data-driven insights in order to inform public policies and drive operational efficiencies in running the health system. Countries in this bracket include England, where it is a leader in decentralised clinical trials and has also used AI to analyse health data on a national scale. Sweden and Denmark both have widespread use of telehealth solutions and the use of AI public sector projects.

IMPERATIVES FOR PHARMA COMPANIES

Given these archetypes, what can Pharma companies do to operate within each country?

Architects: As countries of this archetype have a clear vision but have not yet made it a reality, companies have the opportunity to engage with policymakers to advocate for greater investment in setting standards and building out the requisite infrastructure to enact existing policy frameworks. Companies can also play a key role in shaping the culture and setting expectations by advocating for greater sharing and use of health data in areas where they see significant benefits to the patient

Builders: Steps can be taken to identify and address barriers to using health data provided by existing infrastructure. A collaborative approach with government and academic institutions should be taken to petition for flexible governance frameworks or building out the first partnerships to run pilot projects using this data.

Operators: Pharma companies should look to see how a country’s infrastructure and digital networks can enhance their strategic focus. For example, this could mean running decentralised clinical trials to augment patient recruitment or use genomic data to further offerings in precision medicine.

Elemental analysis

The following section explores each of the twelve elements from the framework used to create the digital maturity scores (see Methodology section for details). The EMEA countries are evaluated as a whole against these twelve elements and some high-scoring examples are showcased. The examples and anecdotes are not exhaustive, but serve to give an indication of a high standard within the cohort.

POLICY

All countries included in this report have at least some policies geared towards digital health, but the differences lie in their breadth and depth. Most of these plans are multi-year undertakings, such as Czechia's Act on Electronic Healthcare 2022-2026³ policy or Switzerland's Health2030⁴ focusing on the next decade.

We can observe that countries just beginning their digital transformation have focused on a bottom-up approach as local hospitals and clinics begin to digitise independently with the support of private investment. There is little national coordination until a policy is put in place. These policies focus on similar areas, such as the ambition to increase the share of EHRs and advancement of telehealth in a safe and secure manner. Interoperability is largely an infrastructure challenge, but policies have recognised it as an important goal to achieve and is called out explicitly in modern digital health acts, such as in the UK's NHS Long Term Plan.⁵

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Highest scoring countries: Countries with mature digital health infrastructure tend to have wide-ranging policies covering all facets of digital healthcare. Estonia is a prime example, with a comprehensive suite of policies covering everything from EHRs to e-prescriptions, e-consultations and e-ambulance.

FUNDING

Sources and clarity of funding are equally disparate amongst countries. Whilst most have earmarked funding for digital health, the specificity differs, and some countries do not have any detailed allocations.

Aside from state funding, countries in the EU often have funding for digital health that is at least partially funded by the EU from sources such as Horizon Europe, Digital Europe, EU4Health and NextGenerationEU (a.k.a. the Covid Recovery Fund). As an example of the latter fund, Poland's country revival plan specifies over €500mn (PLN 2.5bn) for the digitisation of healthcare.

Countries are also often funded from multiple national or regional government agencies, as well as private investment. Countries with higher decentralisation often have funding sourced from regional governments, who can prioritise digital health differently which may lead to neighbouring administrative regions having uneven levels of maturity. Private investment in the healthcare industry has been a high growth area, exemplified by successful digital health start-ups that offer superior user experience, especially in patient-facing tools found in telehealth.

Highest scoring countries: Countries scoring well in this category have clear time-bound milestones that are comprehensive and are mostly well-funded. Germany is one country of note, with programmes such as the Digital Healthcare Act providing €200mn per year. Italy has recently committed to improving its systems networks and digitising its health system through a national post-pandemic resilience package valued at €20bn.

DATA GOVERNANCE

All countries in the EU have stringent data protection regulations as required by the General Data Protection Regulation (GDPR) and countries outside the EU typically have an equivalent data protection act, although these are not necessarily as rigorous.

In India, private institutions and start-ups often use international standards of data protection and with the creation of the National Digital Health Mission (NDHM), better standards have been created but their implementation is proving challenging.

To take another example, Latvia complies with GDPR and access to this data for research and third parties is allowed, albeit tightly controlled. Requests must be approved by a council consisting of members from several government bodies, and the supplied patient data must be pseudonymised.

Highest scoring countries: Strong data protection serves as a foundation from which managed access protocols can be constructed. As such, GDPR-compliant countries score well as a baseline with additional factors such as availability of information to 3rd parties increasing the score. Italy is bound by GDPR but has additional measures on how data can be accessed by the public sector and by private companies, the latter requiring explicit permission from patients. South Africa is a high scorer, with its Protection of Personal Information Act and sharing of data with commercial and academic partners.

INSTITUTIONS

There are various ways countries have organised digital health-related institutions. Some nations have created specific government agencies related to digital health, whereas others choose to allocate the responsibility to pre-existing government institutions. Therefore, depending on the country it may be necessary for a company to work with multiple agencies to comply with digital health requirements. For example, in Bosnia and Herzegovina, largely a decentralised system, there are 13 regional Ministries of Health which are responsible for their own digital health obligations and no central digital health agency.

The institutional setup is continuously evolving with digital maturity as countries attempt to find the path of least resistance to drive transformation.

The existence of multiple interested agencies can cause delays through the added complexity of aligning all parties. In Germany, *gematik* the body in charge of driving digital health counts the Ministry of Health, sick funds, insurers, medical and dental associations amongst its founding stakeholders. Moreover, there are other influential institutions such as the Robert Koch Institute who are a major consumers of health data and guide policy. Another common model is one adopted by many countries who choose to integrate digitisation of health in with a wider national digital transformation strategy overseen by a 'digital advancement' agency. England is in the process of moving its flagship institutions NHSX and NHS Digital under NHS England and NHS Improvement to reduce silos and streamline decision-making.⁶ The institutional setup is continuously evolving regarding digital maturity as countries attempt to find the path of least resistance to drive transformation.

Highest scoring countries: Regardless of the number of institutions responsible for implementing digital health in a country, the key is good cooperation, communication and a clear hierarchy of organisations. Poland and Israel score well in this category, with dedicated institutions driving the digital health agenda (Poland's E-Health Centre [CEZ], Israel's Digital Health Division).

ELECTRONIC HEALTH RECORDS

Nearly all countries covered in this paper have some form of EHRs in place. The key differentiators are the extent of coverage, ownership and data governance. The coverage includes domains such as physician visits, immunisation, infectious disease, pharmaceutical history, laboratory test results and medical imaging amongst others.

In many cases the EHRs are maintained by individual providers or hospitals. As such they can often have interoperability issues due to the differing standards in transmission and storage of the data. Spain is an example of a country that has extensive patient records stored in a free text format. The richness of this data is not easily accessible and advanced techniques such as Natural Language Processing are being used to extract and structure this information.

These are known issues and governments are implementing plans to improve the quality of their EHRs through changes such as enforcing new standards or by improving the mapping and communication between existing systems. One important challenge of note for countries like Germany is the voluntary nature of the planned sharing of patient records. This means physicians and patients both have to see the benefit of uploading data to a centralised database. If managed poorly, this could result in limited coverage and missing patient records.

Highest scoring countries: Few countries excel in this area however Austria is one of note; their ELGA system links health records from multiple institutions into one system accessible by both patients and physicians and is very highly rated in this regard. Estonia launched its Electronic Health Record in 2008, the first in the world to fully implement a nationwide system⁷ and is now used by 100% of patients. Additionally, it uses blockchain technology to further ensure the security of these records.⁸

DATA STANDARDS

Many countries do not have nationwide standards set for healthcare records. Instead, standards are often implemented at regional or hospital levels leading to interoperability issues. This includes both public and private institutions.

Good quality data capture is one of the most important areas to get right as it lays the foundation for analysis further down the line. Like with EHRs, governments are taking strides to increase data quality as they look to work with private parties to introduce common data standards across products. Countries such as Czechia and Spain are adopting international standards such as ICD-11 to improve disease coding, SNOMED CT to capture clinical treatments in a structured way and HL7 FHIR to improve interoperability.

Global implementation of modern standards may one day lead to a greater cross-border understanding of health determinants, giving research institutions the tools needed to track how diseases spread across countries or how genetic and cultural habits determine population health.

Highest scoring countries: In Switzerland, efforts were made from the outset to work with existing international technical standards, for example by following those set by Integrating the Healthcare Enterprise (IHE), a body that advocates for best-in-class standards such as DICOM (for medical imaging) and HL7. France has a comprehensive database of linked health data called the National System of Health Data (SNDS) that brings together health insurance, hospital and disability data amongst others. The SNDS provides a wide range of comprehensive information on the data standards it applies to stitch this data together. As part of My Health 2022 (Ma santé 2022), France is improving its standardisation by introducing a national health identifier that will make referencing of patient data more reliable.⁹

INTEROPERABILITY

Interoperability is a major issue for many countries in this study due to the differences in EHR coverage and data standards. It is often very difficult for institutions or regions within a country to collect health information in data lakes, where most countries can share data at a local level but don't have the infrastructure in place to access data at a national level.

Many countries have made increasing interoperability a priority, but this often remains an aspiration. There are significant barriers in the form of economic incentives and technical capabilities required to carry out the large projects necessary to increase the interoperability of systems.

Moreover, if interoperability does increase in future without international consensus on the best way forward, there is a risk that the formats adopted may still differ between countries, creating divides that hinder multinational data analyses.

Highest scoring countries: Lithuania is more advanced than most in this field, with health providers able to access and share EHRs between healthcare institutions. They are looking to increase interoperability further as part of The Action plan of eHealth System Development Programme 2018-2025.

OMICS

Genomics, and -omics science more generally, is underdeveloped throughout the majority of EMEA countries with only a handful having a national strategy and most having no plan at all. Programmes typically commence through universities on a small scale before being expanded nationally, for example in Belgium a pilot has been set up to screen a small number of cancer patients using next generation sequencing.

It is expected that national genomics plans will soon become more prevalent with around 200 initiatives as of July 2021 according to IQVIA's Genomics Initiatives Database.¹⁰

Highest scoring countries: One leader in this field is England, where the 10-year national "Genome UK" policy paper sets out the governments future strategy of expanding its ambition.¹¹ New initiatives from Genomics England include whole genome sequencing for an additional 300k participants and a new-born screening programme. Denmark is also known for its renowned nationwide programme of whole genome sequencing 60k patients by 2024 and led by the Danish National Genome Centre.¹²

TELEHEALTH

The maturity of telehealth also varies widely between countries, with different services available from both the private and public sector. Mechanisms to codify and therefore reimburse consultations have been developed to encourage physicians to adopt them.

Telehealth services most commonly start off with simpler, easy-to-implement programmes such as online or telephone appointment booking, before moving onto more complex offerings such as video consultations and passive data collection through devices.

Only a handful of countries have no telehealth systems in place. More commonly, a country will have some services but the public awareness and usage of them is very low, for example in Belgium, where teleconsultation is available but not widely used. However, as a result of the COVID-19 pandemic, use of digital tools increased exponentially amongst physicians and patients and this adoption is expected to continue.

Highest scoring countries: Few countries score highly in telehealth, although the pandemic has certainly accelerated the uptake and scores across the board would doubtless be lower without it. Sweden is one of the better scoring countries with widely available telehealth across all its regions. Russia also scores highly with multiple private and public platforms available to patients. Russian telehealth solutions offer a high level of digitisation and are considered an effective way to mitigate capacity constraints.

ARTIFICIAL INTELLIGENCE

The use of AI in health care is a marker for a healthy digital ecosystem as these sophisticated algorithms require vast amounts of clean and structured data to create dependable insights.

We are only beginning to see the emergence of AI in the health sector throughout EMEA as few countries have national AI strategies dedicated to healthcare. Instead, innovation in this space is performed either by the private sector or in academic institutions.

There are exceptions, such as France's National AI for Humanity strategy,¹³ which identifies healthcare as one of four critical sectors for AI usage and has allocated funding towards this. Other countries are also looking to implement policy to further the development of AI in healthcare.

In countries where AI is more widely found we see similar projects in place, primarily due to the advancements in the field from the tech sector. These include using AI to help triage patients and to read medical scans to better identify conditions such as fractures and tumours.

Highest scoring countries: England has a national strategy on AI for health and care formed by the AI hub which helps to drive overarching policy across the UK. England has some of the first real examples of AI projects on health data, piloted by 'Skunkworks', a special group within the AI hub dedicated to rapidly prototyping new concepts.¹⁴ Amongst these projects are identifying patients most at risk of long-term hospital stays, detect anomalies in CT scans and predict negligence claims.

INFORMATION USE

Due to previously mentioned issues such as the disparate nature of EHRs and the lack of interoperable systems in many nations, few are using health data to make evidence-backed decisions on policy or clinical practice.

When health information is actually used in decision making or research, it is often in a limited scope and under strict regulation. For example, many studies

are performed at a local or regional level with data collection relevant to a small cohort of patients linked to a particular disease.

Countries are aware that the use of population level data in routine care is lacking and are trying to lay the groundwork to improve this, for example by solving interoperability issues or creating large data lakes that can be accessed by various stakeholders.

The pandemic has in many ways changed the way systematic data collection has been prioritised and utilised to make decisions on policy. However, the reality is that all this data is still open to interpretation and can be politicised rapidly as evidenced by the different pandemic responses by governments.

Highest scoring countries: Sweden is using real-world data to inform treatment decisions in a variety of areas including oncology, concussions and diabetes. England has begun a pilot called "Heart" using genomic data in routine care to identify individuals with high risk of cardiovascular disease.

VIRTUAL STUDIES

Very little had been done before COVID-19 in the form of decentralised clinical trials and although the pandemic resulted in temporary changes to how trials are monitored, progress is still very slow.

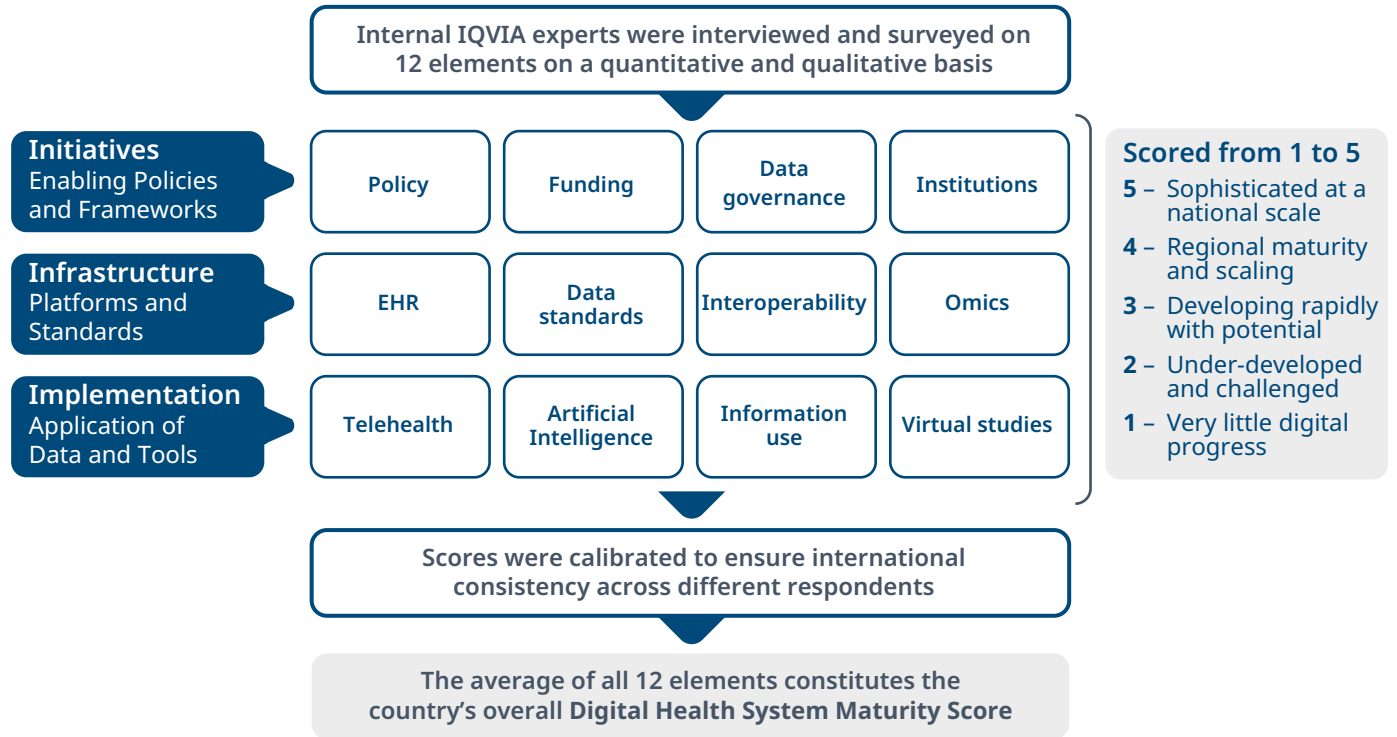
In most countries there are no facilities to run decentralised clinical trials. However, in places where temporary pandemic-initiated changes have been made, these often include measures such as delivering medicines to patients' homes, allowing remote monitoring of sites and submitting evidence remotely.

Some of these changes are expected to be made permanent from the end of the pandemic such as those implemented by Italy.

Highest scoring countries: England has successfully run a decentralised clinical trial in IBS (RELIEVE IBS-D). This trial showed faster patient recruitment than conventional means and allowed the use of wearable devices.¹⁵ Additionally, support services have been set up through NHS DigiTrials where they assist on setting up and running decentralised trials.

Methodology

Framework



Elements considered

Initiatives Enabling Policies and Frameworks	Policy	Funding	Data governance	Institutions	
	<ul style="list-style-type: none"> Importance of digital health in policy Specific and temporal 	<ul style="list-style-type: none"> Earmarked funding Transparency and ease of quantification 	<ul style="list-style-type: none"> Data security and privacy measures Control and ownership of data 	<ul style="list-style-type: none"> Named public and non-profit bodies with power to regulate and influence 	
	Infrastructure Platforms and Standards	EHR	Data standards	Interoperability	Omics
		<ul style="list-style-type: none"> Universal patient ID Type of info e.g. Vx, tests, scans, history Hospital and GP records 	<ul style="list-style-type: none"> Guidance on promoting common operating standards 	<ul style="list-style-type: none"> Open standards and communication between different data owners 	<ul style="list-style-type: none"> Genomics, Proteomics, transcriptomics, etc. Private and public Scale and quality
Implementation Application of Data and Tools		Telehealth	Artificial Intelligence	Information use	Virtual studies
		<ul style="list-style-type: none"> Remote healthcare from diagnosis to medicine delivery Consultation to Doorstep remote services 	<ul style="list-style-type: none"> All initiatives that use health data at a national scale Private ventures providing point solutions 	<ul style="list-style-type: none"> Systematic collection of health data Measurement of patient outcomes Use of data by researchers and policymakers to make informed decisions 	<ul style="list-style-type: none"> Genomics, Proteomics, transcriptomics, etc. Private and public Scale and quality

Country scope

DESK-BASED RESEARCH AND IN-DEPTH INTERVIEWS	SURVEY-BASED WITH CASE STUDIES		
England	Albania	Hungary	Romania
France	Austria	India	Russia
Germany	Belgium	Ireland	Saudi Arabia
Italy	Bosnia	Israel	Serbia
Spain	Bulgaria	Kazakhstan	Slovenia
	Croatia	Latvia	South Africa
	Czechia	Lithuania	Sweden
	Denmark	Morocco	Switzerland
	Egypt	Netherlands	Turkey
	Estonia	North Macedonia	UAE
	Greece	Poland	Ukraine

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About the authors



AURELIO ARIAS
Engagement Manager,
EMEA Thought Leadership,
IQVIA

Aurelio creates topical and forward-looking strategic content relevant to pharma executives and publishes articles, blogs and white papers on a regular basis. He is involved in numerous projects related to increasing access to medicine as well as the interface between healthcare and digital technology. He is considered a subject matter expert in these areas and speaks at numerous conferences worldwide, presents at board-level meetings and engages with consulting projects.

Prior to IQVIA, Aurelio has worked in R&D and in various strategy consulting roles. He holds an MSci in Chemistry from Imperial College London.



AARON WRIGHT
Analyst,
EMEA Thought Leadership,
IQVIA

Based in London, Aaron joined the EMEA Thought Leadership team in 2021. His areas of focus include the rollout of COVID-19 vaccinations globally, as well as RNA therapies as part of the wider field of emerging advanced therapies, digital health systems, and the autoimmune product landscape.

He has an MEng Biomedical Engineering degree from Imperial College London.

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For more information on digital health systems or other Thought Leadership topics, please contact aurelio.arias@iqvia.com

For more information on Payer, Provider and Government solutions, please contact hans.solgaard@iqvia.com

For more information on clinical solutions, including decentralised clinical trials, please contact gjon.mirdita@iqvia.com



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