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Life lessons

Accelerating innovation in life sciences

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The Ayming Institute (AI) aims to help leaders in the private and public sector gain a deeper understanding of the evolving global economy by focusing on three areas.

The first area is sustainability. We believe that the environment and social responsibility are critical issues for businesses today. For this reason, our content aims to help companies integrate these issues into the way they make decisions.

The second area is business development. Through our content, we wish to help companies to develop a stronger business culture and a sustainable approach to growth.

The third area is the people side of the business. With our content, we want to support individuals as they navigate their careers, learn new skills, and find ways to contribute in a world that is constantly changing.

Our strongest commitment is to help organizations better understand how markets are changing, and how they can build better businesses as a result. We aim to do this by providing analysis of the global economy's transformation; sharing our insights through thought-provoking publications, and engaging business leaders in conversations about the economic changes that are affecting all of us.

Executive Summary

The day is coming when with each new birth, a fully sequenced genome could also be delivered. Together, child and dataset would grow in a brave new world of highly personalized medical therapies and preventative healthcare.

If this sounds utopian (or dystopian, given how personal genetic data could be misused) developments now unfolding in data and medical science make this just one of various plausible scenarios for 21st century healthcare.

How we understand, treat and monitor the health of people will be shaped by Big Data and advanced analytical methods, and it's already happening.

With artificial intelligence (AI) and machine learning (ML), insights extracted from a vast and growing pool of patient, research and lifestyle data are set to transform healthcare by uncovering patterns in human biology and diseases that are currently too complex for scientists to decode. These insights have the potential to catapult progress in every research field from fertility to longevity.

AI, ML and Big Data are converging with other technologies including miniaturized sensors, implantables, genomics, 5G, remote patient monitoring, and bioengineering. This mining of new or expanding troves of data generated by genome sequencing, high-volume laboratory testing, patient care, and other clinical and real-world evidence may be in its infancy, but the ramifications are fast becoming apparent.

AI is powering developments ranging from telemedicine and symptom-checker 'doctor apps' to drug discovery and breakthroughs in understanding and treatment of cancers and personalized treatments – such as CAR-T immunotherapy and other advanced cell and gene therapies (also described as 'regenerative medicine').

As in other sectors, COVID-19 has accelerated change and digitalization within the field. The global health crisis concentrated political and business minds as life-saving vaccines were developed in short order. Providing a shot in the arm for the life sciences sector, more investors are backing healthtech and biotech entrepreneurs with greater resources while regulators consider how to create more conducive conditions for growth. The sector is setting new records in investment and activity, spurring scientific progress, that will lead to the development of new treatments.

This Business Note examines three aspects of this burgeoning life sciences arena:

- Modern research areas and methods
- The economic landscape for R&D
- Potential accelerators for growth

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Catalysts for research

While the pandemic intensified the interest of investors in life sciences start-ups and research, their recognition that vast datasets can now be analyzed with ML and AI is the most powerful catalyst.

Digital technology has the potential to capture huge value in healthcare systems around the world, with the benefit of improving care while also driving down its cost. The McKinsey Global Institute estimates the annual savings by 2030 will be in the range of $1.5-3.0 trillion, largely reaped through artificial intelligence, remote monitoring, and automation.[1]

As more and more of the medical data gathered through diagnosis, treatment, monitoring and management of health and modern lifestyles is digitized, it can be accessed on electronic health records and personal devices, shared among patients and healthcare professionals – and aggregated and processed by data scientists and researchers. Data-driven transformation will enable personalization at unprecedented levels and disrupt every area of the value chain across the health sciences.

[1] https://www.mckinsey.com/industries/life-sciences/our-insights/how-the-medtech-industry-can-capture-value-from-digital-health

Accelerated drug development

AI has been shown to accelerate drug development – delivering new therapies and safer drugs at less cost and faster.

Novel drug design is difficult, costly and time-consuming. On average, it takes $3 billion and 12-14 years for a new drug to reach market. Drug discovery is a protracted and expensive stage of drug development, accountable for around a third of overall cost and time. Thousands of molecules may be synthesized to develop a single pre-clinical lead candidate.[2] Applying advanced computational techniques to vast datasets can streamline drug R&D by building holistic and reproducible disease models and developing more specific scalable therapies.

The pipelines of healthcare companies are accumulating phenomenal quantities of new molecules with potential for a multitude of new treatments and therapies. AI can help reduce the costs of developing new medicines by creating better drug designs and finding promising new drug combinations – and it has enabled several drug discoveries so far. In 2020, for example, Ireland's Nuritas announced the first anti-inflammatory to be identified with the help of AI.[4]

The technology is also a potential gamechanger in the repurposing of drugs, which saves costs and shortens the time to market (by 30-60%). This is how Britain's BenevolentAI helped Eli Lilly identify baricitinib, a rheumatoid arthritis drug, as a COVID-19 treatment.[5]

AstraZeneca is also using the company's computational R&D platform to sift massive public and private datasets for new chronic kidney disease therapies.[6]

[2] https://www.ibm.com/blogs/research/2020/06/accelerated-discovery/
[3] https://www.longevity.technology/nuritas-claims-worlds-first-ai-discovered-anti-inflammatory/
[4] https://www.longevity.technology/nuritas-claims-worlds-first-ai-discovered-anti-inflammatory/
[5] https://www.who.int/news/item/14-01-2022-who-recommends-two-new-drugs-to-treat-covid-19
[6] https://www.pharmaceutical-technology.com/news/benevolentai-astrazeneca-partnership/

AI in diagnostics

AI is driving developments in diagnostics as well as drugs.

Radiology was a pathfinder for AI in medicine as the entire imaging process is digitized. Screening digital mammography was an early success. A 2019 study indicated that AI alone, powered by artificial neural networks, could in time be just as effective as human radiologists at detecting signs of breast cancer as well as other conditions.[7]

For now, AI cannot yet function as a diagnostic tool without a clinician's validation, but the scope for increasing speed and efficiency is immense as the technology advances. Integrating AI into different aspects of the radiology workflow can reduce human error as well as drive efficiencies.[8] Going beyond diagnostics, AI can integrate diagnostic imaging, clinical pathology, radiomics and genomics to allow a rapid, single-point-of-care diagnosis, and a tool for precision medicine.

A number of start-ups across Europe are harnessing AI to diagnose and treat conditions, and attracting strong venture capital investment. Portugal's Sword Health is a virtual musculoskeletal care provider combining consultations with human therapists and a personalized AI-powered exercise programme.[9] Others like Ada Health and Kaia Health —offer AI-driven health assessments and therapies for people suffering from illnesses or chronic conditions.

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6748773/
[8] https://researchoutreach.org/articles/transforming-medical-imaging-artificial-intelligence-smarter-healthcare/
[9] https://eithealth.eu/news-article/sword-health-becomes-unicorn/

A faster track for trials

Clinical trials are another area that has been disrupted by AI and digitalization. Overall activity was sustained through the pandemic (in some cases by life sciences companies pivoting their trials from locked-down locales to territories less badly affected). The quest for COVID-19 vaccines and therapeutics led a surge of some 1,200 industry-sponsored clinical trials. Even with their exclusion, participation is rising to record levels.[10]

Traditional three-stage clinical trials can take a decade to complete and cost more than a $1 billion as new medicines go through a battery of tests and trials before they can be authorized. Digital technologies can streamline the process and cost, especially as trial design needs to be adapted for advanced therapies that are developed for small target populations and rare diseases, which compound the difficulties and costs of trial recruitment.

The accelerated development and roll-out of COVID-19 vaccines – the first within just 12 months of sequencing the virus genome – demonstrated the power of concerted public and private investment and scientific know-how facilitated by fast-track regulation.

AI and new statistical analyses make it possible to use real-life data captured from patients along their care pathway to supplement or even inform live clinical trials. Such evidence on the potential benefits or risks associated with medical products allows for innovation in clinical trial design – with fewer and/or more specific recruits, faster and cheaper trials, and predictive information that may increase the chances of approval. UK regulators, for example expedited approval of the Pfizer vaccine for COVID-19 on the back of real-life data linked to its National Health Service (NHS) DigiTrials platform.[11]

Clinical trials can also be streamlined by decentralizing the process, using local healthcare providers, digital tools and mobile research staff. This enables broader trials with a more diverse population, an improved patient experience, and faster and more efficient collection of potentially better data.

[10] Iqvia Institute: Global Trends in R&D – Overview through 2021
[11] LEEM Essais Cliniques 2030 – a study by IQVIA, published March 2022

Data analytics also enables trials to be fully virtual. These 'in silico' studies use mathematical models that simulate the effects of a medical product, intervention or device on a population of virtual patients. It is done using real-life data brought together from multiple sources (patient monitoring devices, clinic check-ups, registers and records, etc). The resultant predictions of molecules that might be effective against a disease can then be verified in the lab and in humans (in vitro and in vivo).

Although the skills required for these trials are at a premium, the cost savings are potentially significant as is the reduction in the risk of catastrophic failures. Fewer patients are required as controls, and therefore, exposed to placebos or less effective standard treatments.

A shift to virtual and personalized clinical trials facilitated by virtual assistants – developed by start-ups such as Italy's Patchai, a 2020 EIT (European Institute of Innovation and Technology) Catapult winner[12] – will increase patient retention and engagement.

As the analytics improve, regulators – especially in the US – are also increasingly open to accepting results from studies with a virtual component. A proactive approach to regulation is essential to encourage the life sciences sector to adopt these smarter, data-driven research strategies – and investors to fund them.

[12] https://eithealth.eu/news-article/patchai-acquired-by-us-based-alira-health/

New economic horizons

The shock of the pandemic prompted a global reprioritization, not just by individuals but also policymakers, business leaders and investors, focusing attention on the life sciences sector.

COVID-19 was a disruptor in positive as well as negative ways. As in most sectors, the crisis had a heavy impact, but there were significant variations between health businesses. Closures of research laboratories halted the development of cell cultures and pre-clinical research. Companies lacking the resources to pivot to remote trials were most severely disrupted. There were also cashflow problems, especially for medtech companies more dependent on sales revenue than their biotech counterparts.

Apart from the emergency state support available for most businesses, governments and health authorities backed life sciences companies gearing up to develop vaccines, diagnostic tests or treatments. The European Union mobilized funding under the Horizon 2020 program for research and innovation, and set up the European Innovation Council fund, which had invested €178 million in company equity by the end of 2020. Healthcare is also a critical sector in national recovery plans, as well as the successor EU framework program for research and technological development to 2027.

Private investment flows

Private funds also flowed in, setting new records for venture capital investment in European healthtech and biotech companies in 2020 and in 2021.

During 2020, health companies raised more than €14 billion in venture and equity capital. Seven countries – Germany, Belgium, France, Netherlands, United Kingdom, Sweden and Switzerland – accounted for €11.3 billion. This included €5.9 billion in venture capital – a 20% jump on the year before. There were nine €100 million-plus transactions, compared with five in 2019.[13]

Stock markets continued to play a key role in financing listed biotech and medtech companies through the pandemic. In 2020 more than €363 million was raised through six IPOs (initial public offerings of shares) on Euronext – the leading stock market for healthcare – and some 400 companies secured nearly €2 billion through secondary raising operations.

Between 2018 and 2020, the UK led the way in capital funding, followed by France, where innovative enterprises can tap a dynamic venture capital market. Like the UK, it also benefits from internationally recognized research organizations. British healthtech companies enjoy strong partnerships too with universities and investment funds, while also raising significant funds from IPOs (initial public offerings of shares) in the US market.

[13] Panorama France Healthtech 2020: https://france-biotech.fr/publications/le-panorama-france-healthtech/

Resurgent biotech

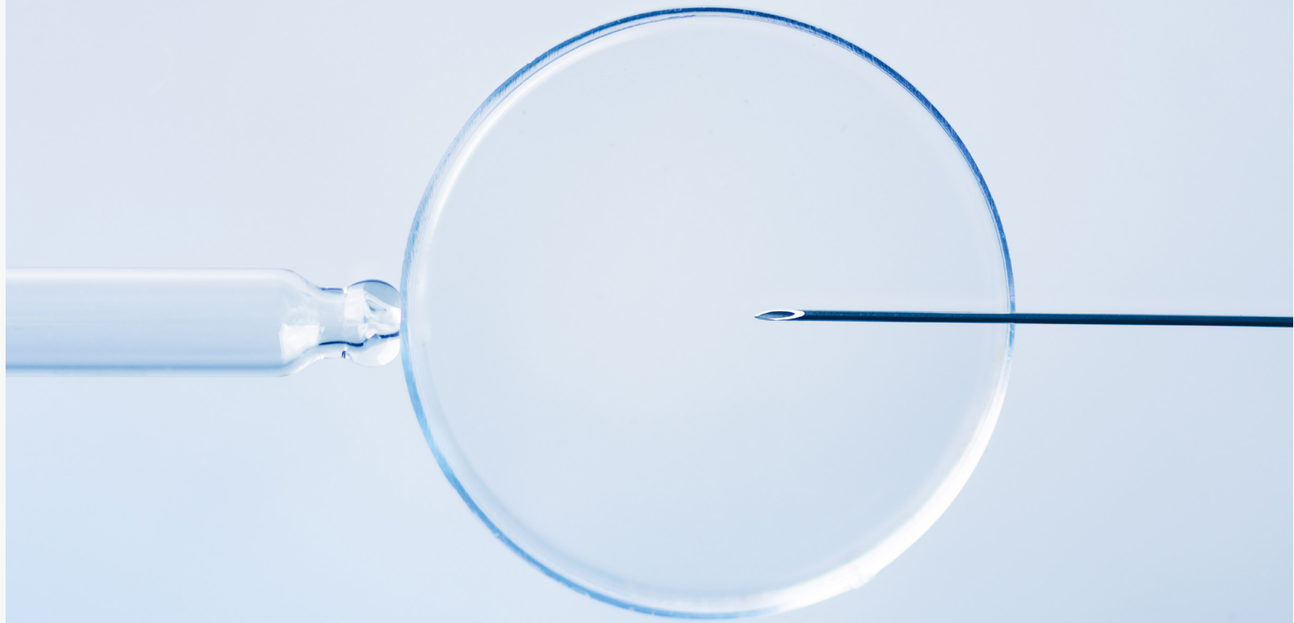
Biotech generally, and the UK's ecosystem in particular, weathered the storm of the pandemic well compared with other sectors, according to a study published at the end of 2021.[14] The UK has one of the most active biotech hubs globally, only lagging the US, which leads the world by a wide margin.

Between 2018 and 2020, twice as many biotechs were founded in the UK (22) than the next most active markers – France and Switzerland (with 11 each) – and they attracted almost a third ($3.6 billion) of the total venture and IPO funding raised by European companies.

But Europe overall is making up ground fast on other regions. Europe's rate of product launches is increasing at a faster rate than other key geographies and making progress in closing the gap with market leader US.[15] Europe is roughly on par for early-stage innovation, and its growth capital is maturing, though IPOs on European stock markets are still dwarfed by those across the Atlantic. The continent also lags badly behind both the US and China when it comes to translating its research power a into pipeline of new medicines.

For these and other reasons, the UK biotech sector is heavily dependent on the US market, especially for funding later-stage development. More UK start-ups choose to go public on US exchanges, whereas more European firms scale their operations before being acquired or invested in by big pharma partners.

[14] The UK biotech sector: The path to global leadership – McKinsey & Company
[15] https://www.mckinsey.com/industries/life-sciences/our-insights/infographic-the-mckinsey-biotech-innovation-index



Notable examples include Owkin, a French start-up applying ML to medical research and developing predictive AI to detect biomarkers for diseases and model treatment outcomes. The company had already partnered with Roche before a $180 million investment by pharmaceuticals company Sanofi made Owkin a unicorn at the end of 2021.[16]

More such partnerships and acquisitions will follow as Big Pharma seeks to exploit the full potential of AI-assisted drug and therapy discovery.

In 2021, venture capital investment in both healthtech and biotech start-ups globally continued to surpass previous records, reaching $63 billion and $41 billion, respectively.[17] Seventy new healthtech and 28 biotech unicorns were created in just one year (taking the totals to 202 healthtech and 192 biotech).

The combined enterprise value of healthtech and biotech start-ups founded since 1990 is now $4 trillion. Healthtech companies globally have reached a combined value of $1.7 trillion – that's 4.5 times the level in 2017. Biotech companies are valued at $2 trillion, another four-fold increase.

While the US leads in venture capital investment, Europe is the fastest growing region. In 2021 global healthtech received a $10 billion injection, 2.4 times the 2020 total. Europe's share is at an all-time high, while China's shrank as the rest of Asia quickly catches up.

Following the unprecedented surge in pandemic-driven private investment in 2020, biotech companies continued to attract healthy support through 2021. European companies saw a 20% increase (the same rate as the US) to $6.5 billion. Most of this growth is AI-powered.

[16] https://sifted.eu/articles/ai-biotech-owkin-unicorn/
[17] https://dealroom.co/uploaded/2022/01/Dealroom-report-health-jan2022.pdf?x75805

Tax relief for R&D

R&D tax credits may not attract headlines but they remain an often-critical source of funds, especially for smaller, independent medtech/biotech companies. The relative generosity of the relief provided for innovation-related expenditure varies across Europe. It was notable from the early stages of the pandemic, however, that in most states, the tax authorities accelerated the processing of R&D credit claims to ease the cashflow pressures on SMEs.

As research shifts increasingly from the lab to the computer suite, the scope of R&D tax relief needs to widen, embracing the significant costs of acquiring and analysing large datasets.

The UK is already doing this. With effect from April 2023, all companies applying for tax relief for their R&D projects – irrespective of sector – can claim for expenditure on mathematical analysis, associated software, data sets, cloud computing, and data collection and cleansing by suppliers; (in-house staff costs for compiling data are already eligible).[18] This approach contrasts with other countries, such as Germany, where only staff costs are counted in its less mature R&D regime, which was only created a couple of years ago.

As data science plays an ever-more important role in life sciences research, this recognition will become increasingly valuable to healthtech companies, giving them a competitive edge over counterparts in jurisdictions with tighter R&D tax credit criteria.

[18] https://www.gov.uk/government/consultations/the-scope-of-qualifying-expenditures-for-rd-tax-credits-consultation

The role of regulation

Regulation is another area where the life sciences R&D, and the growth of the sector in Europe, risk being impeded.

In the area of clinical trials innovation and regulation, for example, the US and UK are far more advanced than their European counterparts, according to a 2022 review by LEEM, the organization representing pharmaceutical companies operating in France.[19]

The US owes its status as world leader in this area to proactive regulatory and governmental agencies that are open to changes and willingness to accept promoter risk. Advantages in the UK include a favorable and homogeneous regulatory framework at the national level and between agencies, and the government's enthusiasm for promoting clinical research, including digitalization and patient-centric solutions.

Spain ranked second in Europe for its general commitment to clinical trials, except for real-life data as it lacked a clinical data registry. In France, industry and academia are promoting various changes, which are being adopted by supportive regulatory agencies. However, regulatory obstacles remain due to a lack of harmonization and collaboration with promoters, and information system infrastructure.

Italy and Germany are lagging, hampered by the regional organization of their health and research systems and delay in digitalization in Germany, where its 2019 Digital Health Care Act has had mixed results. Also, by focusing on domestic entrepreneurs, Europe's largest health market may be alienating international investors.[20]

The USA is also significantly ahead when it comes to incorporating virtual testing in clinical trials. Whereas Europe has been the more active than other regions, including the US, in bringing digital therapeutics and combined medical devices to market, tighter EU regulations have caused a slowdown. From May 2021, EMA's requirements for CE markings make access to the digital therapy market more complex. In the US, the Federal Drug Administration favors certification of technology providers for digital therapies to accelerate future market access.

Meanwhile, for the UK, the loss of ready access to EU funding and its seamless common market access was expected by the scientific community to damage R&D in life sciences as in other sectors. The MRA's move from London the Netherlands was a blow to the UK's status as a center for clinical research on the continent.

[19] LEEM Essais Cliniques 2030 – a study by IQVIA, published March 2022
[20] https://sifted.eu/articles/europe-germany-digital-health/

However, the country's regulators have since made radical changes to shore up its position. From January 2021, the UK's Medicines and Healthcare Products Regulatory Authority (MHRA) removed the requirement for comparative clinical efficacy trials in most cases of biosimilars – potentially highly valuable biologics similar to licensed medicines.[24]

Life sciences companies in the innovative drugs sector are also attracted by another proactive regulatory process introduced after Brexit – the Innovative Licensing and Access Pathway (ILAP). For example, Albert Labs, a psychedelic medicine start-up listed on the Canadian Securities Exchange, opted to conduct clinical trials in the UK.[25] It is developing a psychoactive compound for treatment of depression and anxiety in cancer patients who cannot take traditional anti-depressants.

ILAP guarantees drug developers a constant feedback loop from the MHRA. They can also communicate directly with the National Institute for Clinical Excellence (NICE) the agency that acts as gatekeeper for medicines in the UK's National Health Service. The promise of streamlined communications and approvals is a significant lure to agile drug developers, and part of a wider plan "to create a world-leading UK clinical research environment," and the grander ambitions of a national strategy for the life sciences sector.[26]

The success achieved by fast-tracking approval of the AstraZeneca-Oxford vaccine for COVID-19 – ahead of regulators in EU states – also taught the UK another lesson. The MRHA's willingness to make decisions based on real-world evidence ("extended data sources") offers the life sciences sector another route to faster trialling of new therapies and targeting of the most suitable patients.

As a final example, another post-Brexit regulatory change at least partly offsets the lack of automatic access to the huge EU market for UK-approved medicines. The MRHA joined the Access Consortium of national regulators in October 2020. Drugs licensed in member countries, such as Australia, Canada, Singapore and Switzerland, should gain approval more quickly in the UK, and vice versa.

[24] https://www.centerforbiosimilars.com/view/uk-regulators-seek-response-on-waiving-comparative-efficacy-testing
[25] https://sifted.eu/articles/albert-labs-psilocybin-psychedelic-ipo/?utm_source=sailthru&utm_medium=email&utm_campaign=flagship_newsletter&utm_content=11-03-2022&utm_term=wants_main_newsletter
[26] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/995863/the-future-of-uk-clinical-research-delivery-2021-to-2022-implementation-plan.pdf

Accelerating the sector's growth

The life sciences sector in Europe may be separated from the US, and China, by a gulf in R&D investment or commercialization, but it is growing fast and attracting investment, much of it AI-inspired.[27]

As data becomes the lifeblood of research and innovation, many of the critical factors that could accelerate this growth hinge on the availability of quality information as well as analytical capabilities to extract value from it.

[27] https://sifted.eu/articles/into-the-metaverse-this-years-healthtech-trends-to-watch/

How to share data?

Reconciling the widest possible access with data privacy concerns and cybersecurity risk is an extremely complicated challenge, and highly sensitive.

Following a public outcry, the UK had to shelve plans to collect and share the National Health System's general doctor records for 55 million patients with third-party researchers. During the pandemic, easier access to these longitudinal NHS datasets was critical to the speed of COVID-19 research, including the University of Oxford's RECOVERY trial that identified dexamethasone – a drug credited with saving more than a million lives worldwide.[28] However, GPs (general medical practitioners) and millions of people opted out of the later "data grab" amid concerns that patients could be identified even from the pseudonymized data.[29]

Yet, the unprecedented international partnership coalescing around pandemic preparedness indicates that greater cross-border collaboration may be possible in other areas.[30] Silos must be broken down to pool sufficient reliable, longitudinal and interconnected data – on the healthy as well as those who are ill – to unlock the full potential of computational science for innovation in drug discovery, diagnostics and precision medicine.

Also, limitations and gaps in data may lead to inaccuracy or bias in symptom checker apps. Concerns that the chatbot of telehealth giant Babylon failed to identify serious conditions were investigated in the UK,[31] which dropped plans to regulate apps as medical devices in line with the EU. A university study also raised concerns about diagnosing skin cancer with AI skin systems trained using imagery predominantly of white people.[32]

[28] https://www.nhsx.nhs.uk/key-tools-and-info/data-saves-lives/
[29] https://keepournhspublic.com/nhs-data-grab-what-next/
[30] https://www2.deloitte.com/us/en/insights/industry/public-sector government-trends/2022/global-health-partnerships-collaboration.html?id=us:2sm:3li:4diUS175190:5awa:6di:MMDDYY::author&id=gx:2sm:3ls:4livesocial:5:6abt:&pkid=1008653
[31] https://www.independent.co.uk/news/health/nhs-symptom-checker-app-safety-complaints-b1813142.html
[32] https://www.theguardian.com/society/2021/nov/09/ai-skin-cancer-diagnoses-risk-being-less-accurate-for-dark-skin-study

Just as the pandemic encouraged data sharing, data partnerships could bridge these gaps. The Beyond 1 Million Genomes project is creating a network of genetic and clinical data to give 23 countries in Europe cross-border access to one million sequenced genomes by 2022.[33] It is developing technical specifications for data quality, technical infrastructure, and ethical, legal, and social standards that would establish European best practice.

Blockchain and other new technologies could resolve the privacy and security concerns. Estonia uses blockchain to control access to citizens' digital health records, which it aggregates. The World Economic Forum (WEF) believes that other "game-changing advances" in ML can revolutionize healthcare without sharing either patients' records or healthtech companies' valuable AI models. Algorithms can be designed instead to reinforce each other in their collective analyses.[34]

Patient privacy and intellectual property of the underlying data and models would be protected by sharing technical features via a broker system. Researchers would share resulting insights but not sensitive information. For proofs of concept the WEF points to the Global Alliance for Genomics and Health and Europe's ELIXIR. The WEF has also developed a governance model to drive innovation through its genomic data consortium with Australian Genomics and Genomics4RD.

Other data platforms are being developed. MIDATA is a Swiss nonprofit that supports cooperative regional and national data platforms for global research projects. Scientists can also pay to use Synthace's cloud platform, remotely automating experiments and sharing information using ML and AI. Owkin's 'federated learning' technology empowers research with data sets from across different countries and systems.[35]

The costs and hurdles involved in constructing an international mega-data platform are high. McKinsey estimates, for example, $27 billion just for a neurology platform covering one million people. But this would be paid back by the value of novel therapies, more efficient R&D, and longer, healthier lives.[36]

Technologies for storing vast amounts of data and compression standards would also be needed to support such platforms. Before that, significant investment is required for digitization and upgrading and harmonizing IT infrastructure so that intra/international systems are interoperable. Digital maturity varies widely across Europe; the complexity and cost of the task depend on the health service model, public/private provision, and number of agencies.

Whatever its eventual form, a shared pan-European space for interoperable, secure, and GDPR-compliant health data would provide a huge boost to research, development and innovation.

[33] https://b1mg-project.eu
[34] https://www.weforum.org/agenda/2021/10/advances-ai-enable-medical-research-without-sharing-data/
[35] https://www.weforum.org/organizations/owkin
[36] https://www.mckinsey.com/industries/life-sciences/our-insights/better-data-for-better-therapies-the-case-for-building-health-data-platforms

Smoother, smarter regulation

Concerted efforts can accelerate innovation and bring scientific breakthroughs to market sooner. Apart from the example of COVID-19 vaccines, the time from patent filing to launch in the US had fallen to its lowest level by 2021.[37]

Regulators do perform expedited reviews and issue emergency/temporary approvals in certain circumstances, and they are more comfortable with the use of AI to assist drug and treatment development. There is scope for extending this more proactive approach post-COVID and harmonizing standards and protocols, not least in relation to frameworks for use of real-life data and to clinical trials. The EMA is committed to Big Data training for its teams analyzing study designs.[38] Novel trial designs – including virtual, remote, decentralized and adaptive methods – should be encouraged and facilitated. In 2021, some 8% of trials worldwide were accelerated in this way.

Greater collaboration among manufacturers, researchers and regulators – for example, 'horizon scanning' (as happens to some extent in Italy, the UK and North America) – would help to anticipate the burden of evaluating innovative drugs and their potential impact on health systems.[39]

Reimbursement is a more complex issue, especially where healthcare delivery and payment are fragmented between public and private providers and other agencies. Effective innovation needs to be incentivised and fairly rewarded at a national level. France has followed Germany by allowing state insurance to reimburse healthcare apps.

But other factors may be more critical. One of the biggest challenges for European healthtech and biotech entrepreneurs is fragmented local public markets that cannot attract the critical mass of investors, analysts and banks available in the US.[40] Pan-European harmonization of digital health that doesn't require country-by-country validation would spur greater interest from international investors.

[37] Iqvia Institute: Global Trends in R&D – Overview through 2021
[38] LEEM Essais Cliniques 2030
[39] https://www.leem.org/publication/sante-2030-une-analyse-prospective-de-linnovation-en-sante
[40] https://sifted.eu/articles/europe-germany-digital-health/

Conclusion

Since the pandemic, it is not just the economic landscape that has changed for life sciences. All sectors of industry and commerce are rethinking their approach to innovation, as Ayming's International Innovation Barometer 2022 survey showed. Two-thirds of respondents (across all industries) stated that the fast-track development of COVID vaccines had given them a blueprint for reconsidering how they might solve problems more quickly. Not surprisingly, among biotech and medtech companies, the consensus on this point was overwhelming.

We welcome the growing realization among policymakers that the life sciences sector is worthy of targeted support, that regulatory regimes must adapt to accommodate innovation while safeguarding public safety and privacy, and above all, that concerted effort is required to enable strategy coordination across borders in Europe.

For their part, life sciences companies and their financial backers need to invest in digital tools and upskilling, so they can realize the full potential of AI and data-driven approaches to accelerate progress – from drug analysis and trials to diagnostic capabilities.

Governments can incentive and support that investment, not least by reviewing and updating their R&D tax credits regulations to reflect the new and exciting realities emerging in life sciences innovation.

Contributors

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Working as an Innovation performance consultant with a background in Biomedical Engineering and Management, Ysaline manages a portfolio of clients working in the Life Sciences sector. Her objective is to help companies by optimizing their access to various grants, by promoting their participation in R&D projects or by improving their ability to invest in R&D through external financing.

The Benchmark

A simple way to compare and understand international R&D Tax schemes.

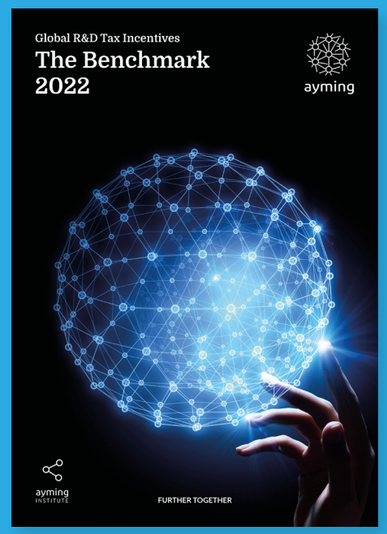
Applying for an R&D tax incentive can be confusing and time-consuming, especially if you're trying to compare different schemes from different countries.

There are a lot of different R&D tax incentives out there, and it can be hard to figure out which one is the best fit for your company. Not only that, but each country has their own set of rules and regulations when it comes to applying for these incentives.

To help you to this process, Ayming has leveraged its global R&D tax expertise to create an annual independent review of R&D incentive schemes around the world called The Benchmark.

This white paper provides an easy way to compare key international R&D tax incentive schemes, based on two important metrics: Generosity of the scheme and Ease of Application.

You'll also get the opportunity to have global overview specific of R&D tax incentive with the help of our 23 country profiles. These profiles contain an overview of each R&D tax incentive scheme, including application process, benefits, eligible claim period and more.



With this guide, you will be able to answer critical questions such as:

- Is foreign-owned R&D eligible?
- Must R&D occur in the country?
- How many previous financial years are claimable?
- Is pre-approval required?
- Are other R&D incentives available?
- What is the level of review or inquiry expected?

If you're looking for a simple way to compare international R&D Tax schemes or to get an easy-to-understand overview of your country's scheme, *The Benchmark* is for you!

DOWNLOAD FOR FREE

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