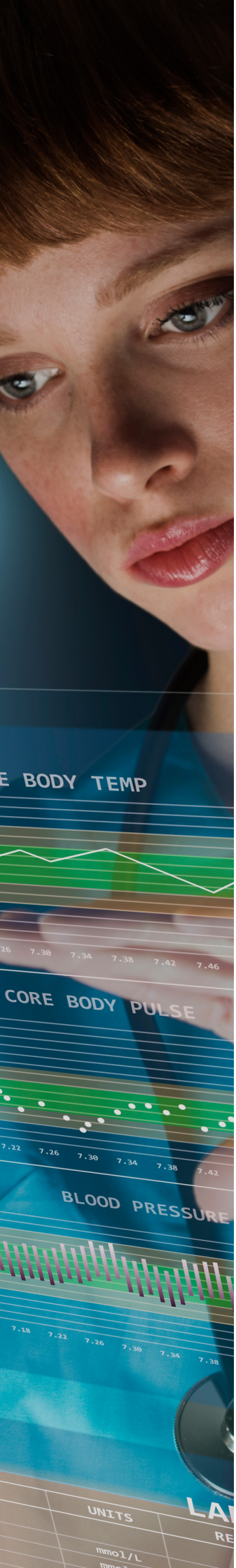
KPMG

Trends in the Life Sciences Industry

Cyber Security for Life Sciences

Summer Edition 2022



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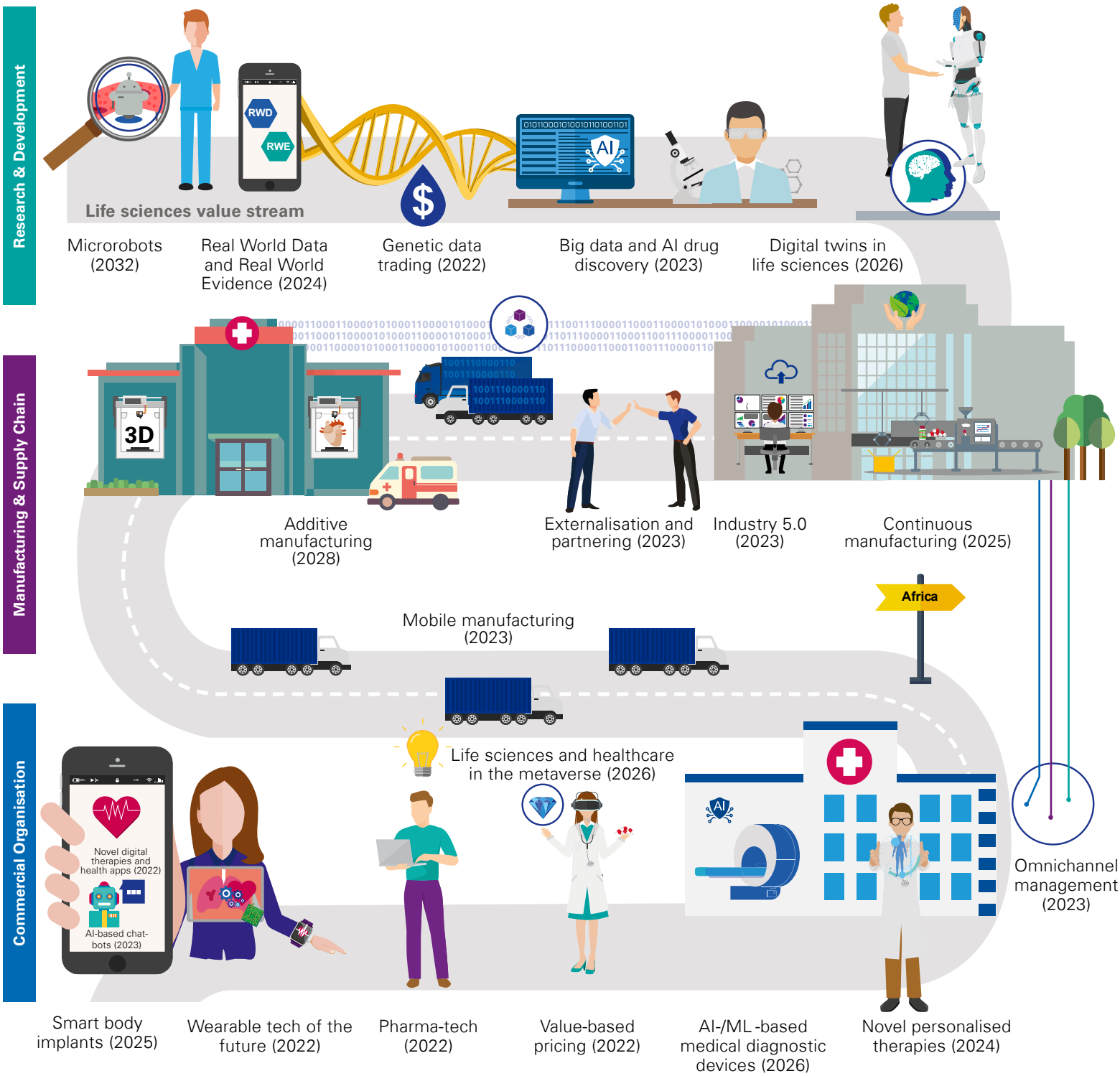

Cyber considerations for Research & Development

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- Customer identity and access management
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- Data governance & privacy
- Secure software development
- 3rd-party security
- Cloud security
- Smart product cyber security

Introduction

Dear reader

Digitalisation and data are on everyone's mind and are expanding in leaps and bounds in the life sciences industry. Notably, if more data becomes available, competition will shift from who has the best data to who can analyse it best[1]. We identified more than seventy life sciences trends in our previous editions of this report in 2020[2] and 2021[3], including major data-driven innovations. And more exciting trends are emerging on the life sciences horizon, covering artificial intelligence-(AI-)based smart body implants, smart and connected diagnostic devices, the use of blockchain technology, decentralised production as well as Industry 5.0.

The future of the life sciences industry will be digital and data-driven, but what about digital security?

To tackle this question, we have focused this current report on trends with a digital or data-driven footprint. We have outlined the cyber risks resulting from each of the innovations and suggested key cyber security measures. The past has taught us that ignoring such risks can not only cause considerable financial damage and reputation issues but can also be life-threatening[4].

We have structured the report into three sections along the Life Sciences Value Chain. Trends in the section "R&D" range from Real World Data and digital twins to large-scale ***in silico*** research data sets. Cyber risks associated with those trends include clinical trial data loss as well as data manipulation. Strategies such as digital rights management should be considered as countermeasures. Trends in the section "Manufacturing and Supply Chain" cover robotic process automation, 4D printing as well as modular container systems for decentralised production and therapy. The higher level of personalisation and automation in manufacturing leads to vulnerabilities such as system and production manipulations. Potential counterstrategies include smart production device cyber security. Trends in the section "Commercial Organisation" cover smart body implants and wearables, as well as novel personalised therapies. Cyber risks in this section specifically include loss, manipulation or mis-feeding of AI algorithms; specific countermeasures include secure software development.

What became clear during our analysis is that "one size fits all" does not fit anymore. The right message (or therapy) has to be selected for the right person at the right time and delivered through the right channel. This applies to omnichannel management in the same way as it does to personalised therapies.

We have created this report with input from experts from KPMG and KPMG Law in Germany, KPMG in the UK, KPMG in Switzerland and external sources. It also features insights and interviews from our life sciences and cyber security leaders and experts.

To maintain the focus, we have restricted ourselves to the key cyber risks and strategies. Nevertheless, general security measures such as the establishment of a security management system with corresponding status and risk reporting or preventive security measures and measures for detecting and responding to attacks need to be taken into account by life sciences companies. In addition, the General Data Protection Regulation (GDPR) but also specific regulations such as the Guidance on Cybersecurity for Medical Devices of the EU and upcoming regulations from the Food and Drug Administration (FDA) and the Medicines and Healthcare products Regulatory need to be considered by life sciences companies[5].

In today's rapidly changing world, it is essential for life sciences companies to take advantage of the growth opportunities offered by digitalisation and data. At the same time, the dangers of the digital world need to be analysed and preventive protective measures as well as detective controls and capabilities to respond to cyber attacks need to be initiated. Without security, the trust of patients, consumers and society is at risk. And once trust is lost, it is hard to win it back.

Enjoy the report and stay safe and healthy.

Thomas Hillek

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Research & Development

Research & Development

The R&D functions of life sciences companies will use large virtual data sets. Traditional randomised clinical trials will be complemented by Real World Evidence and digital twins. In drug discovery, large *in silico* data sets will be screened to speed up the process, increase the hit rate in the search for suitable molecules, and save costs.

Trend #1

Genetic data trading (2022)

Innovation ★☆☆

Cyber Risk ★★★

Declining costs for genome sequencing (Figure 1) and increasing markets for direct-to-consumer genetic testing (DTC-GT)[6] could be one driver for a vibrant genetic data trading market of the future. Companies develop different approaches to offer incentives for patients and healthy individuals to share their genetic information. LunaPBC, Inc., for example, offers a platform on which users can upload their gene analyses to make them available to research institutions and pharmaceutical companies and in doing so become shareholders of the company[7]. Nebula Genomics, Inc.[8] and Zenome.io Ltd.[9] both use blockchain technology to allow customers to monetise DNA information by receiving tokens in return and simultaneously to keep the identities of users anonymous. Other providers such as Genelink, S.L.[10], MyHeritage Ltd.[11] and Ancestry Ireland Unlimited Company[12] offer free or low-cost analysis of genome data in exchange for sharing the genome information. By partnering with these platform providers, life sciences companies can gain access to the collected data for applications such as drug development. GlaxoSmithKline plc, for example, invested USD 300 million to obtain exclusive rights of 23andMe, Inc. data up to and including 2022[13].

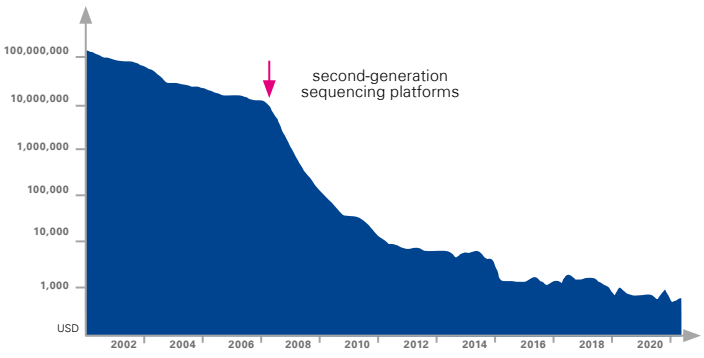


Figure 1 | **Genome sequencing costs are declining.** The cost for sequencing a human genome has declined from more than USD 100 million in 2001 to less than USD 1,000 today. Adapted from genome.gov/sequencingcosts[14]

Trend #2

Big data and AI drug discovery (2023)

Innovation ★★☆

Cyber Risk ★★★

AI applied on big data offers revolutionary opportunities to transform the otherwise time-consuming, expensive and complex drug discovery process[15,16]. Examples of big data in life sciences include next-generation sequencing (NGS), other large amounts of high-value and high-quality microarray data plus the technology to analyse the data[17,18,19]. Recently, multiple deals between large pharma and AI drug discovery companies have been announced including IKTOS and Pfizer Inc.[20], Insitro, Inc. and Bristol-Myers Squibb Company[21], and many more[22]. The digital biotechnology company Recursion Pharmaceuticals Inc. is cooperating with Roche Holding AG and Genentech, Inc. to industrialise drug discovery with machine learning (ML) from big data[23]. In what is known as the MELLODDY (Machine Learning Ledger Orchestration for Drug Discovery) project, ten well-known pharmaceutical companies such as Merck KGaA, Novartis AG, Bayer AG, GlaxoSmithKline plc, and Boehringer Ingelheim Pharma GmbH & Co. KG together with public partners aim to develop a ML platform model with more than one billion drug-development-relevant data points and hundreds of terabytes of image data[24]. The EU regulation on clinical trials provides the platform DARWIN EU (Data Analysis and Real World Interrogation Network) for unified access to and use of health data from the EU. The European Medicines Agency's (EMA) goal is to ensure the necessary big data infrastructure and the publication of DARWIN EU by 2023.

Trend #3

Real World Data and Real World Evidence (2024)

Innovation ★☆☆
Cyber Risk ★★★

Real World Data (RWD) refers to patient health status data that is captured outside of randomised clinical trials. According to the FDA, RWD can be collected from different sources including electronic health records, product and disease registries and even mobile devices. By analysing RWD, Real World Evidence (RWE) is generated to support therapy decisions, to demonstrate the post-market efficacy and safety of drugs in everyday practice and to thereby complement clinical trials.[25] Pharma companies apply RWE in vaccine development, medication testing and even in designing novel digital therapeutics[26,27]. Pear Therapeutics Inc. used RWE to assay patients with opioid use disorder under a digital prescription therapy[28]. To learn more about the efficacy and long-lasting benefits of multiple sclerosis medicines, Merck KGaA has started a RWD study and found out that their drug MAVENCLAD® improves the quality of life of Relapsing-Remitting Multiple Sclerosis (RMS) patients by enabling longer mobility[29]. In 2021, the FDA introduced the COVID-19 Evidence Accelerator aiming to investigate how COVID-19 treatments and vaccines affect people in the real world[30]. Pfizer Inc. recently took advantage of RWE to assess the effect of a COVID-19 booster vaccination in Israel[31]. The AI research project OPTIMA (Optimal Treatment for Patients with Solid Tumors in Europe Through Artificial Intelligence), which includes 36 partners from 13 countries, such as Bayer AG, Pfizer Inc. and AbbVie Inc., will design, develop and deliver the first interoperable, EU-privacy-compliant platform for RWD in oncology[32].

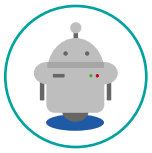
Trend #4

Digital twins in life sciences (2026)

Innovation ★★☆
Cyber Risk ★★☆

Will each of us have a digital health twin in the future? Digital twins are a virtual replica of real-world physical objects or processes. They serve as models in several industries and can be used to optimise quality and to monitor and predict events[33,34]. Digital twins are also applied to develop and produce new COVID-19 medication. Together with the FDA, software development company Dassault Systèmes UK Limited has launched the "Living Heart Project", which will test medical products and virtual surgeries on virtual twin organs to predict the outcome and effectiveness of treatments, reduce animal testing and save lives.[35,36]

Similarly, the EU-supported Neurotwin project models the interaction of electric fields in the brain, which should lead to new treatments for Alzheimer's disease[37]. The AI startup Unlearn.AI, Inc. wants to revolutionise randomised clinical trials by replacing the control arms with digital twins that can function as virtual placebo patients[38]. GNS Healthcare has even developed a data-driven *in silico* Patient™ for head-to-head clinical trials which simulates the individual response to drugs[39]. In addition to the use of digital twins in R&D, they are applied in life sciences companies for manufacturing, supply chain, business and new product modeling, medical devices, as well as logistics[40].



Trend #5

Microrobots (2032)

Innovation ★★★
Cyber Risk ★★☆

Small robots will move through our bodies to deliver drugs, perform micro-surgery or take tissue samples – sounds like science fiction? Companies and academia around the globe are working towards this vision. Researchers from China have performed first proof-of-concept studies with 4D-printed (see also trend #11), fish-shaped microrobots which are magnetically guided to cancer cells and can release a chemotherapy on site when a pH changes[41]. A team at the Max Planck Institute for Intelligent Systems has developed a building block system, similar to Lego®, for the fabrication of miniature robots. With this, they aim to boost variety and thus capabilities for applications in robotics and biomedical engineering.[42] Furthermore, researchers at the University of Zurich have developed a 3D-printed microrobot drug delivery system, to deliver drug payloads via blood vessels in the human body[43]. Similarly, the Los Angeles-based company Bionaut Labs is developing remote-controlled micro-robots (Bionauts™) for precision-targeted medicine application. Recently, Bionaut Labs and Candel Therapeutics, Inc. have announced a strategic collaboration for the precise delivery of oncolytic viral immunotherapy in brain tumors.[44]

Research and Development: Cyber risks and countermeasures

Trends for R&D in the Life Sciences Industry

- #1 Genetic data trading
- #2 Big data and AI drug discovery
- #3 Real World Data and Real World Evidence
- #4 Digital twins in life sciences
- #5 Microrobots

Key cyber risks

Clinical trial data loss or manipulation

With the digitalisation of clinical trials and the use of RWD and digital twins, data loss or manipulation either by accident or a malicious attack would have tremendous negative effects including delayed launch times for medication and the loss of trust by patients and societies.

Misuse of access to sensitive (genetic) data

If unauthorised parties get access to sensitive genetic data, this does not only have implications for the patients themselves. A large proportion of the genomic information, including potentially diseased genes, overlaps with the genomic information of a patient's relatives. Attackers could try to steal the information from all partners processing this data in the healthcare ecosystem. The loss of trust by patients and societies would impact the data custodians.

3rd-party risk in R&D

In basic research and clinical trials, several parties work together, e.g. researchers in international institutes and life sciences companies, HCPs, study nurses, etc. Special attention should be paid to the additional cyber risk connected to third parties. Special protection should be given to data shared with other institutions as well as to the other institutions themselves. A cyber attack on one partner can affect several partners in the ecosystem.

Loss or manipulation of AI in R&D

AI algorithms could be sensitive intellectual property leading to a clear market differentiator. In the event of theft, this could have a significant financial impact. The manipulation of AI algorithms could lead to false assumptions in the development of drugs and in clinical trials. In addition, mis-feeding/mis-training of AI algorithms could lead to false conclusions and research results.

Manipulation of microrobots

Smart and connected products like microrobots are a potential target for attackers. Due to network connectivity – often a direct Internet connection – they can be accessed from anywhere and vulnerabilities can be exploited. The misuse of these Internet of things (IoT) devices through denial-of-service (DoS) attacks and the manipulation of these devices can lead to safety risks for patients. The loss of trust in these products can lead to severe market obstacles for the manufacturer.

Violation of regulation, e.g. patient data privacy

The secure storage and processing of sensitive personal patient data is subject to many different regulations and privacy laws around the world. Non-compliance can result in draconian fines and other legal consequences. This includes connected medical devices (including microrobots) and in some definitions even software as a medical device and AI as a medical device.

Key cyber security strategies

Digital rights management in clinical trials

The access to and usage of clinical trial data needs sound controls during the whole lifecycle and across the boundaries of all involved parties. A proper digital rights management can protect the data itself including strong cryptographic measures to preserve confidentiality and integrity of the clinical research data.

Identity & access management

Mature processes for identities and related access rights need to be implemented to access and work with highly sensitive (genetic) data. This includes identity verification, user lifecycle management, access rights management & verification of researchers, healthcare professionals (HCPs) and other involved roles have to ensure that only the right people have the right access at the right point in time.

3rd-party security in R&D

A third party security framework needs to be developed, addressing all involved institutions/parties. This should include but is not limited to defined security controls and security maturity levels, contractual obligations, certifications requirements (for products and third parties) as well as third party security audits and continuous monitoring.

Secure software development

Secure software development procedures for AI algorithms used in R&D and related software should be implemented and applied. This includes continuous source code scans and security testing based on DevSecOps. In addition, software quality should be enhanced by secure software training procedures.

Smart product cyber security

As with other smart products, sound best practices for product cyber security need to be followed and independently tested for microrobots. This includes considering the whole lifecycle of the microrobot as well as the interaction with related services, e.g. in case of software updates. Furthermore, proper customer communication needs to be established in case of attacks or with related services.

Data governance and privacy

A sound data governance and privacy management system needs to be implemented. This includes but is not limited to data subject notification processes and the data subject rights processes (information, rectification, erasure). Security control should be based on a privacy risk assessment. This has to consider legislation such as the GDPR and all other relevant national laws and regulations, e.g. regulations for smart medical devices such as the Guidance on Cybersecurity for Medical Devices of the EU, upcoming regulations from the FDA and the Medicines and Healthcare products Regulatory.

Expert Interview: *Success will no longer be measured by profit alone.*

Thomas Hillek

Partner, Head of Life Sciences & Chemicals, EMA, KPMG, Germany

1

What are the top three life sciences trends you consider to be most relevant in today's and tomorrow's world? And why?

Clearly, personalised medicine is and will remain a key trend in the life sciences industry. Therapies are becoming increasingly customised, ranging from individualised cancer vaccination to personalised fertility treatment. Another growing trend in life sciences is the combination of established approaches with new digital methods and advanced technologies in R&D and manufacturing. Smart technologies such as AI, blockchain and 4D printing will enable the use of RWD, digital twins and microrobots. Providing accurate and unbiased information, this can lead to positive effects such as advancements in drug research or the acceleration of drug approval times. A third major trend is the increased deployment of digital solutions in the diagnosis and treatment of diseases. Driven by the pandemic, we observe a growing number of health apps and digital wearables but also smart implants for patients as well as increased research into AI-based diagnostic devices to improve both quality and outcome of care.

2

Which novel therapies do you think are most innovative? What developments do you see on the horizon?

In particular, mRNA-based vaccination technology, which has been used globally for COVID-19 vaccination. This technology is also advanced as immunotherapy in clinical trials for individualised cancer therapies. I foresee an increased focus in research on immunotherapies for the future. I also consider bioprinting, which could minimise the amount of surgery and thus risks to patients, as well as precision surgery, which combines robotics and AI tools to perform accurate procedures, as innovative therapeutic methods to maximise treatment outcomes for patients.

3

What are the most pressing challenges that life sciences companies are facing? How can they be tackled in order to remain relevant in the market?

Life sciences companies have always lived with and from constant research and innovations. Therefore, it is especially relevant for these companies to deal already today with the question of which innovations, developments and new methods can be used for research and treatments in the future. For this purpose and to keep up with the speed of the development of new trends, it is recommended to enter into more agile cooperations with start-ups and technology companies in the future. Another key challenge is that life sciences companies will be held much more accountable for their sustainability contribution in the future. Success will then no longer be measured by profit alone, but rather by the positive impact on the environment as well as societal health. To be successful, companies must develop sophisticated Environmental, Social and Governance (ESG) strategies and be more engaged with the communities to address more unmet health needs.

Manufacturing & Supply Chain

Manufacturing & Supply Chain

To support the needs resulting from more personalised medicine, the life sciences industry will be moving away from the one-size-fits-all supply chains to advanced segmentation and parallelisation. This is increasingly being enabled by additive, mobile and continuous manufacturing and other means, allowing the life sciences industry to be as close to the point of care as possible. In addition to the physical enablement, the application of Industry 5.0 with new technologies such as AI, IoT and RPA is supporting the digital enablement and thus accelerating these developments. As a result, supply chains will also be more resilient, more agile and more sustainable in the future.

Trend #6

Industry 5.0 (2023)

Innovation ★★☆

Cyber Risk ★★★

Society is facing major global challenges which are taken into account in the concept of Industry 5.0. Industry 5.0 is based on the key pillars of Industry 4.0, including the IoT, the cloud, AI, big data, Robotic Process Automation (RA), blockchain, digital twins for personalisation of customer needs and increased productivity, better scalability and cost reduction (Figure 2, A and B)[45,46,47,48]. Industry 5.0 puts human-centricity, resilience (e.g. resilient value chains, better adaptability and flexibility of processes) and sustainability (environmental, social and governance) into focus (Figure 2, C). Innovations should be responsible and should focus not only on profit maximisation but also on the benefit to society and the environment.[49] Due to ever-shorter product lifecycles, Merck KGaA and Evonik Industries AG, both together with Siemens AG are focusing on the concept of modular production to become more flexible and to cut CO2 emissions[50,51]. By the end of 2021, Boehringer Ingelheim Pharma GmbH & Co. KG had opened a new tablet factory as a smart factory, a major step towards more flexibility and sustainability[52]. To achieve better performance, agility and to be more environmentally friendly, Sanofi S.A. invested in its own smart manufacturing system[53,54].

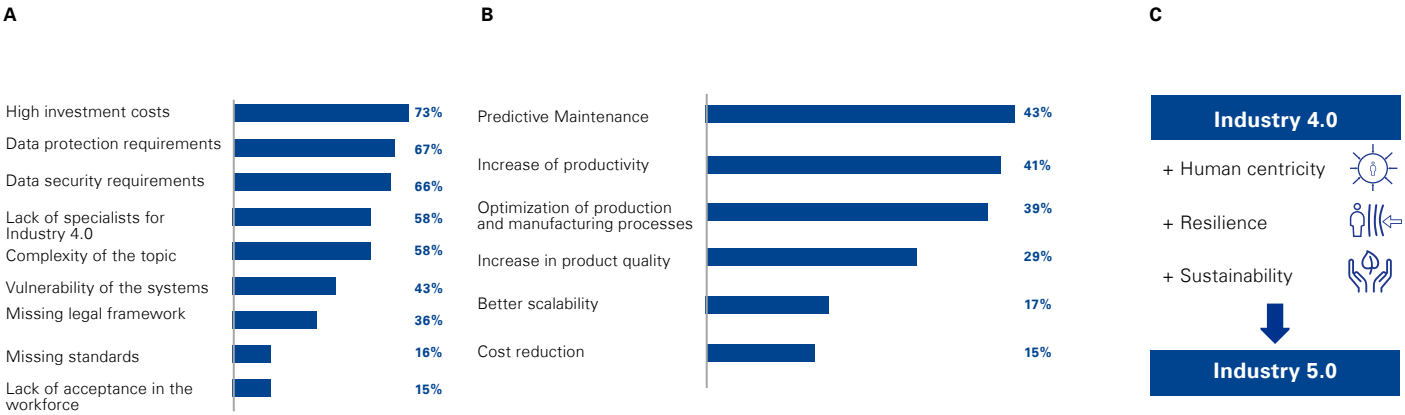


Figure 2 | High investment costs are barriers to the implementation of applications which in turn bring significant benefits to Industry 4.0 and 5.0. (A) Barriers to the use of Industry 4.0 applications. (B) Advantages of AI application in the context of Industry 4.0. Percentages represent the opinion of 552 industrial companies, with multiple responses possible. Adapted from Bitkom Industry[55]. (C) A broadening of the Industry 4.0 concept leads to Industry 5.0.

Expert Interview: *Advanced segmentation in pharmaceutical manufacturing and supply chains.*

Roger van den Heuvel

Partner, EMA Life Sciences Strategy Lead, KPMG, Switzerland

Dear Roger, we are seeing advanced segmentation in pharmaceutical companies. Can you elaborate on this and share considerations for pharmaceutical manufacturing and supply chains?

The complexity of future portfolios of pharma companies will continue to increase. Just think about the impact cell & gene therapy will have on manufacturing and supply chains. Whilst there have been attempts to differentiate within current supply chains, most are still being run in a similar fashion with a focus on optimising average costs and delivery performance. In a world with new modalities, requiring very different manufacturing and supply chain approaches, and customer experience being increasingly crucial, optimising averages is likely to result in underperformance on most if not all metrics. Segmentation based on real-life customer behaviours and financial metrics such as True Economic Contribution[1] will allow firms to identify multiple parallel supply chains and tailor the corresponding management approach, e.g. the performance metrics.

Do you think that this will all lead to a whole new manufacturing and supply ecosystem in which traditional pharmaceutical companies need to re-define their role?

I believe advanced segmentation will further boost the trend of externalisation as the new segmentation and the underlying data will allow more accurate make or buy deliberations supported by more tailored performance metrics to manage external supply chains and thereby enhance their chance of success. The increasing relevance of the customer experience with various customer groups to satisfy will further push postponement strategies, ideally to the point of care, and also fundamentally alter the build-up of such ecosystems.

Manufacturing and supply chain ecosystems will thus become major strategic levers going forward, and traditional pharma companies will likely move toward coordinating multiple bespoke manufacturing and supply ecosystems in parallel, which will require very different management capabilities.

Where do you think pharmaceutical companies struggle the most regarding this increase in segmentation and how can a strategic advisor support this?

They will need to understand the strategic potential and relevance of their manufacturing and supply chain footprint, be willing to develop and simulate various non-incremental scenarios on a regular basis and be able to tap into or build the relevant and secure databases to support such simulations. These are all areas where a strategic advisor should be able to challenge and support.

1 Economic Contribution = (Gross Margin – Other Operating Costs) – (Attributable Invested Capital x Cost of Capital % Threshold)

Net profit | Asset/Capital charge

Trend #7

Externalisation and partnering (2023)

Innovation ★☆☆
Cyber Risk ★★★

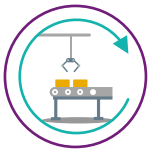
Current supply chains are built for scale. Novel personalised medicines and new modalities, such as cell and gene therapies (C&GT) but also a growing demand for more agility and sustainability as well as greater transparency from raw material to production to the patient, require new capabilities. Life sciences organisations are therefore increasingly partnering with external providers[56]. C&GT supply chains, for example, are generally more complicated than traditional drugs due to specific temperature (- 80°C to -196°C) and timing requirements, the personalised nature and the task of maintaining the integrity of the drug[57]. To assist in the manufacturing, quality management, regulatory support but also logistics and many more activities, Contract Development and Manufacturing Organisations (CDMOs) and Contract Manufacturing Organisations (CMOs) including Charles River Laboratories[58], Thermo Fisher Scientific Inc[59], Advanced BioScience Laboratories Inc[60] or Viralgen[61] offer their services to smaller or virtual biotechs up to large pharma players. COVID-19 vaccine production was also largely outsourced to partners including Catalent, Inc[62] and Lonza Group AG[63]. An investment in new partners and integrated third-party management is necessary to gain new capabilities and optimise the logistics of an organisation in order to meet novel requirements.

Trend #8

Mobile manufacturing (2023)

Innovation ★★☆
Cyber Risk ★★★

Mobile manufacturing could reduce the unequal distribution of access to life-saving medicines between developed and developing countries. BioNTech SE has now taken another step towards improving vaccine supply worldwide by establishing an end-to-end production network which enables the production of mRNA-based vaccines. As a standardised concept, the BioNTainer complex is replicable and, due to its container set-up, shipment by lorry, ship or plane is possible to all continents. Starting in mid-2022, the first BioNTainers are to be delivered to Africa, marking a major step forwards for vaccine access including not only COVID-19 vaccination but any mRNA-based vaccine, such as potential future vaccines against malaria and tuberculosis.[64] Similarly, researchers at MedMagLabs at Griffith University's School of Medicine together with Royal Wolf Australia (United Rentals Inc.) have converted a shipping container into a laboratory, known as the "C-Lab". It could bring maggot therapy closer to the point of care, revolutionising disaster and conflict wound care.[65] Other mobile turn-key lab solutions are being provided by companies such as WALDNER Holding SE & Co. KG[66] to support on-site SARS-CoV-2 testing capacities worldwide and Global Life Sciences Solutions USA LLC[67] for the production of virus-based biotherapeutics.



Trend #9

Continuous manufacturing (2025)

Innovation ★★☆
Cyber Risk ★★★

Batch manufacturing is the dominant mode of manufacturing for the pharmaceutical industry. The concept of continuous manufacturing (CM) however may provide large potential in terms of faster processes, better scalability, higher quality and lower costs for the life sciences industry. In CM, the feeding of input and the transformation and removal of output is performed continuously[68,69]. The Massachusetts Institute of Technology (MIT) spin-off Continuus Pharmaceuticals provides the CM platform Integrated Continuous Manufacturing (ICM) for small-molecule pharmaceuticals and has recently announced the receipt of a USD 69.3 million US government contract to facilitate domestic production of vital medicines[70]. The breast cancer drug Verzenio®, recently approved by the FDA for HR+ HER2- high Risk Early Breast Cancer, is Eli Lilly and Company's first solid oral drug produced with CM[71]. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), a non-binding body which was founded amongst others by the FDA, the European Commission (EC) and Japanese regulatory bodies, has developed a guideline on CM to address key technical and regulatory considerations and to promote harmonisation. The guideline is currently under public consultation and will be issued in a final version in 2022.[72,73]

Trend #10

Additive manufacturing (2028)

Innovation ★★★
Cyber Risk ★★☆

3D printing creates customised, personalised solutions thanks to its flexibility in terms of geometry, structure and material variation[74,75]. Based on these properties, various medical devices such as prosthetics or implants are produced using 3D printing[76]. Henkel AG & Co. KGaA and the US start-up Nexa3D produced the world's first additively manufactured connected stethoscope for tele-medicine[77]. Merck KGaA and AMCM GmbH are cooperating with the goal of producing tablets and investigational drugs through 3D printing[78]. Bioprinting is used to create organ-like structures which imitate natural tissues by printing cells and biomaterials[79,80]. Researchers from the University of Zurich are developing 3D-printed personalised implants such as artificial

spinal discs or personalised bone plates with cellulose fibres, biodegradable nanoparticles, a universal carrier ink and customised bioresorbable airway stents[81,82]. Thanks to biodegradability, this method could help to minimise the number of additional surgeries and thus additional risks for patients.[83,84] Compared to 3D printing, 4D printing considers the structural and functional change of the printed object under various environmental influences over time. Novel 4D printing techniques are being developed by Stratasys Ltd., Autodesk Inc. and the Self-Assembly Lab from MIT[85]. Applications in life sciences could be self-reconfiguring proteins or the design of stents which would unfold in the body[86].

Manufacturing & Supply Chain: Cyber risks and countermeasures

Trends for Manufacturing & Supply Chain in the Life Sciences Industry

- #6 Industry 5.0
- #7 Externalisation and partnering
- #8 Mobile manufacturing
- #9 Continuous manufacturing
- #10 Additive manufacturing

Key cyber risks

Industry 5.0 system manipulation

Attackers could get access to Industry 5.0 environments and manipulate or stop processing. Depending on the specific case and scenario, this could lead to a financial loss or product quality issues if e.g. material verification activities are manipulated. This could quickly lead to a significant impact if not detected in time.

Production manipulation/outage/shutdown

Hacking of production machines can lead to manipulation of (vital) data including verification data or the outage of production facilities. The financial impact of non-availability of production sites can be significant and can severely damage the reputation of the life sciences company.

3rd-party risk and supplier risk in manufacturing and supply chain

The data exchange with suppliers and CDMOs/CMOs as part of an integrated supply chain or remote access by 3rd parties to production lines gives hackers a larger attack basis for obtaining access to clients' operational systems.

Loss or manipulation of decentralised production

Smart production devices such as 3D (bio) printers, often with a direct Internet connection, can be accessed from anywhere and vulnerabilities exploited. In addition, decentralised production such as 3D (bio) printers and medicine production in containers is vulnerable to physical on-site attacks. Manipulating the properties of 3D- (bio-)printed products or therapies by hacking printers or manipulating printer layouts can harm the safety of patients. Intellectual property (IP) can be stolen und used to copy a life sciences company's products.

Violation of regulation, e.g. patient data privacy

The secure storage and processing of sensitive personal patient data is subject to many different regulations and privacy laws around the world. Non-compliance can result in draconian fines and other legal consequences.

Key cyber security strategies

IT security & security automation

Best practices in security should be implemented with regards to RPA environments. This includes but is not limited to privileged access management and patch management. Furthermore, continuous monitoring should be designed and implemented to identify malicious behaviour in real time and react accordingly.

OT security

OT security for life sciences production sites should be integrated in the overall cyber security framework. The cyber framework needs to be adjusted to OT specifics to guarantee the high availability and safety requirements of (pharmaceutical) production processes. Security controls and capabilities should be implemented to prevent, detect, respond to and recover from OT cyber incidents.

BCM/Service Continuity

A business continuity management (BCM) system and a service continuity concept should be implemented to allow end-2-end controlled recovery from outages. Recovery priorities need to be defined and recovery plans should be implemented and thoroughly tested. Communication to relevant stakeholders (e.g. patients, customer, HCPs) needs to be implemented and tested.

3rd-party security in manufacturing and supply chain

For the supply chain and production as well, a 3rd-party security framework needs to be developed. This should include but is not limited to defined security controls and security maturity levels of the supply chain and production partners, contractual obligations, certification requirements (for products and parties) as well as third-party security audits and continuous monitoring.

Digital rights management

Access to and use of decentralised production, e.g. 3D (bio) printers and layouts as well, need sound controls during the whole lifecycle and across the boundaries of all involved parties. A proper digital rights management can protect the patient and 3D printing data itself including strong cryptographic measures to preserve confidentiality and integrity of the 3D (bio) printers and layouts.

Smart production device cyber security

In smart production devices, sound best practices for cyber security need to be followed and independently tested. This includes the whole lifecycle of the product as well as the interaction with related services, e.g. in case of software updates. Proper (customer) communication needs to be established in case of attacks or vulnerabilities.

Secure software development

Secure software development procedures for 3D (bio) printers and related software should be implemented and applied. This includes continuous source code scans and security testing (e.g. based on DevSecOps). In addition, 3D (bio) printer software quality should be enhanced by secure software training procedures.

Data governance and privacy

A sound data governance and privacy management system needs to be implemented. This includes but is not limited to data subject notification processes and the processes around data subject rights (information, rectification, erasure). Security control should be based on a privacy risk assessment. This has to consider legislation such as the GDPR.

Expert Interview: *It is essential that security is strategically aligned to the business strategy.*

Caroline Rivett

Partner, Global Cyber Security
Life Sciences Leader, KPMG, UK

Jayne Goble

Director, Cyber Security, Cyber in Healthcare, KPMG, UK

Dear Caroline, dear Jayne, we see massive changes and trends in the Life Sciences sector's manufacturing and supply chain. Which are the major risks on a global scale from your perspective?

Caroline: There are massive strategic shifts going on within life sciences due to the impact of digitalisation. There's increasing personalisation of medicines and therapies as life sciences companies explore how medical, clinical, and production data can be used to improve treatment and care. Different manufacturing and supply chain strategies will be needed depending on the volume and level of personalisation. Certain production strategies, such as for high-volume medicine pill production, will be volume driven and require large streamlined facilities; other strategies, such as for personalised large-molecule therapies, which are more individualistic to patients, will lead to smaller production facilities located in hospitals. The security strategies for large-volume medicine production have a high emphasis on availability and integrity, and include consideration of OT security and access management in production systems. Personalised large-molecule medicine therapies will be led by protecting the confidentiality and integrity of data and information flows, with connected device security becoming very important. In conclusion, it is essential that security is strategically aligned to the business strategy to maximise the security's effectiveness.

Jayne: In addition to this, there is another aspect which is impacting most life sciences organisations: The 3rd-party security risk. More life sciences organisations are onboarding 3rd parties to speed up production, but they need to consider what and how their security stance might change when they involve third parties. Considering the massive changes in operations of the Life Sciences sector, M&A and carve-outs, it is understandable that organisations want to find agile and low-impact solutions to complete effective security evaluations of the security risks as the environment changes and new network/sister organisations are onboarded. Also remarkable is that there is a growing sophistication in attacks, especially malware attacks in production and end-user devices. One example is malware that is focused on damaging or sharing patient data information, which is worth a lot and sold on the black market.

Can you elaborate on regional differences regarding those risks?

Caroline: Some of these risks may be territory specific. Privacy and data protection are good examples. Global companies are required to comply with different privacy laws and regulations across the world, which requires centralised monitoring and management of the requirements of the different regulations to keep track of what the requirements are.

In addition, companies must also strategically review, assess, and transform how they transfer and process personal data globally following the introduction of increasingly stringent regulations by countries (such as Schrems II in the EU and PIPL in China) to retain individuals' personal data within their territories. Life sciences companies are increasingly using medical and clinical data in research, clinical trials and even in production. They use anonymisation and pseudonymisation techniques to protect personal data, and control risks around potential breaches with privacy-enhancing technologies such as encryption.

Jayne: A major difference are distinct cyber security regulatory guidelines for connected medical devices and other devices in different countries. Every country now has a version of these guidelines and the effort required to harmonise them is increasing all the time. However, there will always be differences, largely as a result of different laws such as data protection or telecoms laws. In July 2020, for example, the European medical device regulation was published containing cyber security regulations for devices for manufacturing as well as medical devices. In the recent update of this regulation, the scope has been broadened, and now also software and AI are handled as a medical device. Country-specific differences range from different product scope to different responsibilities and include post-market regulations which the life sciences company is responsible. A third point would be the specifications. In the EU, for example, there is a set of specifications which need to be followed including DevSecOps elements which need to be built around the devices.

Which are your top three countermeasures which global life sciences companies should be taking into account regarding their value chain?

Caroline: 1) Define and understand their key assets, where the threats to them arise from, and the risks that they face 2) Build security into the underlying design of their systems and processes, taking a zero-trust approach to minimise the extent to which attackers can move within their systems 3) Determine how to build resiliency into their technology and have well-thought-through plans to recover from attacks.

Jayne: From the perspective of a likely rapid increase in IoT, I think there are a number of countermeasures that can successfully secure the environment, without limiting the potential of new service models and performance benefits that can be achieved through increased interoperability across the ecosystem. The first essential countermeasure is to have an understanding of the architecture and the devices and technologies that are employed, as these create a foundation towards better understanding the various security and privacy issues and their impact. Once this understanding is formed, organisations can begin to develop a tactical understanding of the controls and precautions that should be taken in order to strengthen the security of a medical IoT environment. Such as having perimeter defence mechanisms, network security controls, device and OS update guidelines, device security controls, security testing plans (e.g. penetration testing), and proper incident response plans. Finally, I would add that organisations should highlight some of the key features and trends that they can anticipate in upcoming years in terms of Medical IoT security. For example, the emergence of AI has marked a huge turning point in the IoT health care market and is helping the growth of the MIoT market. Hence, it is evident that the significant use of AI-powered solutions will assist in real-time security monitoring.

Commercial Organisation

Commercial Organisation

Customers of life sciences companies, e.g. patients and HCPs, will benefit from a higher degree of personalisation. This includes smart body implants and wearables, and personalised therapies including digital and seamless experiences through an orchestrated omnichannel management.

Trend #11

Value-based pricing (2022)

Innovation ★★☆

Cyber Risk ★☆☆

A study on the US health care system showed that about 25% of health care spending is wasted[87]. The reasons include missed prevention opportunities, fraud and abuse, overuse, administrative waste, clinical inefficiencies and high prices.[88] With the growing number of novel, innovative, personalised and often cost-intensive therapies, the approach of value-based pricing is becoming increasingly relevant. In value-based pricing, the actual value of a therapy results from measuring health outcomes compared to the cost of delivering these outcomes (Figure 3). Benefits of value-based pricing include broader access to previously inaccessible geographies for pharmaceutical companies, avoidance of wasteful spending and reduced risks for payers, improved health outcomes for providers and obtaining faster access to novel therapies for patients.[89] Enlace Health, Inc.[90] and Lyfegen HealthTech AG[91] are two examples of software providers that connect life sciences companies with healthcare payers, which simplifies the shift from fee-for-service to value-based care. In August 2021, it was announced that Lyfegen HealthTech AG was partnering with Johnson & Johnson GmbH and a leading Swiss hospital to implement its value-based healthcare platform[92]. Similarly, Novartis AG and Gilead Sciences, Inc. have introduced value-based pricing for CAR-T cell therapies[93].

Trend #12

Wearable tech of the future (2022)

Innovation ★☆☆

Cyber Risk ★★★

The use of digital wearables, in some cases connected to smartphone apps, in the form of smart clothing and jewellery such as watches, rings or necklaces has become increasingly established in recent years for tracking vital signs, detecting symptoms of illness or monitoring patients.[95,96,97,98] This enables applications in a wide range of areas including birth control offered by start-ups such as Lady Technologies Inc.[99] and Ovy GmbH[100]. In collaboration with the Massachusetts General Hospital Center for Artificial Intelligence, researchers at the MIT Computer Science Artificial Intelligence Laboratory recently developed the "EIT-kit", which allows users to design and produce customised wearables using a 3D editor. The resulting 3D-printed devices can measure and visualise motion and internal muscle activity.[101,102] Abbott Laboratories announced that it is developing a new category of consumer wearables called Lingo, which can translate the body's unique language into actionable data that can be used to track and measure overall health and well-being at any time. The sensor technology is designed to detect key signals in the body such as glucose, ketones and lactate, and in the future can even monitor alcohol levels[103].

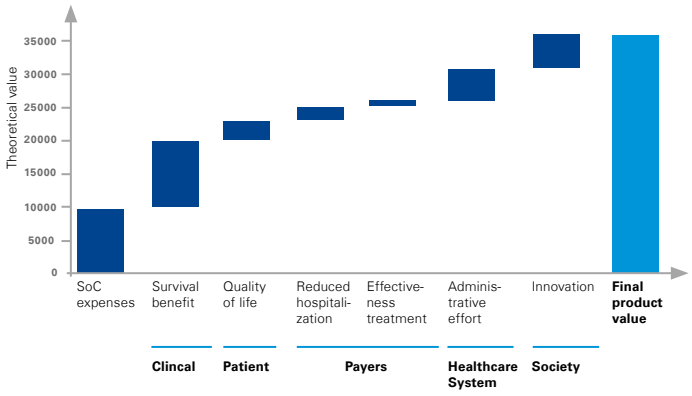


Figure 3 | Various individual values contribute to the final value of a theoretical product. X-axis, Value category; Y-axis, Theoretical value; SoC, Share of Cost. Illustrative, presented metrics are not exhaustive. Adapted from KPMG[94].

Trend #13

Novel digital therapies and health apps (2022)

Innovation ★★☆
Cyber Risk ★★★

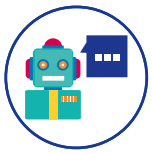
Digital health can be provided through prescription-only digital therapeutics (DTx) and health apps. Both offer remarkable opportunities for patients to manage, track and evaluate health indicators, as wearables collect large amounts of data in real-time[104,105]. Today, AI-powered apps are being used for well-being and to improve sleep, fitness and nutrition as well as in medical areas such as mental health, oncology, neurology and metabolic disorders, providing preventive as well as therapeutic and rehabilitative care.[106] Novel DTx and health apps that promote mental health are being developed in various directions across multiple target groups.[107,108] Besides start-ups, which offer prescription-free health apps[109,110] and DTx listed in the German digital health applications (DiGA) directory[111], pharmaceutical companies are increasingly entering the digital and mobile health market, which is growing rapidly[112]. Novo Nordisk Pharma GmbH for example provides a free diabetes management app with its brand Cornerstones4Care®[113], Sanofi S.A. developed its first official digital health app with myDose Coach®[114], and the mySugr GmbH digital diabetes diary of Roche Diabetes Care GmbH became part of the "Digital Health Region of the Future" initiative of the German Federal Ministry of Health[115].

Trend #14

Pharma-tech (2022)

Innovation ★☆☆
Cyber Risk ★★☆

Collaboration between major pharma players such as Pfizer Inc. and BioNTech SE with Merck KGaA, Novartis AG, and Sanofi S.A. to support the production of their COVID-19 vaccine has been further driven by the pandemic[116]. But with the rise of digital health services, even new market players are continuously entering the industry and novel cooperation models between big pharma and tech players are emerging along the value chain. In 2021, Bayer AG and Microsoft Corporation entered into a strategic partnership to optimise digital capabilities across value chains by building a new cloud-based set of tools and data science solutions[117] and Merck KGaA and Koninklijke Philips N.V. announced their collaboration to advance personalised fertility care through remote monitoring, cloud-based platform services and AI-powered ultrasound diagnostics[118]. In addition to open collaboration with new market players, strong M&A strategies for inorganic growth are another key driver in the field of digital health. Examples include Novartis AG's acquisition of the DTx player Amblyotech LLC[119] and Roche Diabetes Care GmbH's acquisition of the diabetes management startup mySugr GmbH[120].



Trend #15

AI-based chatbots (2023)

Innovation ★★☆
Cyber Risk ★★★

Chatbots are computer programs which use text, and natural language processing (NLP) to mimic human conversations. Chatbots in the pharmaceutical industry can improve the patient, HCP and employee experience by providing information and at the same time reduce costs. Chatbots based on NLP are not yet capable of making a primary diagnosis but can be used to assist in this process[121,122]. For example, Novo Nordisk Pharma GmbH's chatbot Sophia[123] and Norgine GmbH's (Plenvu®) AVA[124,125] can answer questions related to the correct ingestion and treatment procedures including diabetes or colonoscopies. Pfizer Inc.'s chatbot Fabi is regularly approached by consumers with product availability questions and chatbot Maibo has been launched in Japan for HCPs[126]. In addition, Bayer AG provides medical product information for HCPs via the chatbot AMI, which can be reached online or via speech assistants[127].

Trend #16

Omnichannel management (2023)

Innovation ★☆☆
Cyber Risk ★★☆

The COVID-19 pandemic has accelerated the transformation of both HCPs and patients into "digital natives", who are now seeking a consistent, seamless and personalised experience across digital, remote, and in-person channels. Companies such as Roche Holding AG, Sandoz International GmbH, Merck Sharp & Dohme Corp., Grünenthal GmbH and Novo Nordisk Pharma GmbH are looking at how they can optimally implement comprehensive and orchestrated omnichannel management and succeed with their channel mix. Aspects such as revealing common pain points which HCPs and patients experience along the patient journey and the use of AI- and ML-powered customer data platforms are particularly important, and many pharmaceutical companies seek support from external services.[128,129,130] To drive more connected and personalised content for HCPs, the US General Medicines team at Sanofi S.A. is focusing on modular content and channel-specific templates to shorten the lengthy review process before bringing content to market[131].

Trend #17

Novel personalised therapies (2024)

Innovation ★★★
Cyber Risk ★★☆

One size does not fit all – this applies to many therapies and drugs used to treat diseases. The pharmaceutical industry has recognised this problem and is driving forwards the development of personalised medicine. As defined by the European Union, personalised medicine is "[…] tailoring the right therapeutic strategy for the right person at the right time […]"[132]. One industry example of personalised medicine is the Individualized Neoantigen Specific Immunotherapy (iNeST) from BioNTech SE in collaboration with Genentech, Inc., which includes an on-demand manufacturing process for cancer drugs based on the mutation profile of the patient[133]. Moderna, Inc. is using a similar strategy and is running a phase 1 study for their personalised cancer vaccine mRNA-4157, which encodes several neoantigens, in combination with Merck Sharp & Dohme Corp.'s Keytruda®[134,135]. The challenge companies face in developing personalised medicine is currently that global, cross-academia and cross-industry collaboration is needed as displayed by long-standing consortia such as WIN[136], ICPerMed[137] and the Personalized Medicine Coalition (PMC)[138]. Overcoming this hurdle will pave the way for the widespread adoption of personalised medicine.

Trend #18

Smart body implants (2025)

Innovation ★★☆
Cyber Risk ★★☆

Will data-driven smart devices with real-time analysis revolutionise the field of medical implants? Several inter-operative next-generation technologies have been developed in the field of orthopaedics. The Smart Knee™ implant Persona IQ ® from Zimmer Biomet Holdings, Inc. and Canary Medical Inc. collects kinematic data from patients to support post-surgery treatment[139]. The smart implant SmartFuse®, which recently received an FDA Breakthrough Device Designation, aims to stimulate, steer and monitor bone growth following spinal fusion surgery[140]. An interdisciplinary research team from the Saarland University is developing intelligent bone implants that detect and respond to incorrect weight bearing on a fractured bone[141]. As described in the last edition of this trend report, several companies are developing brain monitoring devices. Mojo Vision Inc. aims to develop smart lenses including a microLED display, smart sensors and small, biosafe batteries which could correct vision and provide augmented reality (AR) experiences[142]. Furthermore, smart dental implants which could resist bacterial colonisation and conduct phototherapy[143] or bioartificial devices which act like organs, e.g. kidneys[144] or pancreas[145], are currently under development.

Trend #19

AI-/ML-based medical diagnostic devices (2026)

Innovation ★★★
Cyber Risk ★★★

Medical diagnostic devices such as x-rays, CT, MRI and mammography are used to detect anomalies, including breast or lung diseases[146]. Today, the MRI scan can take up to 90 minutes[147]. In the future, AI/ML could help by analysing and detecting diseases earlier, faster and more accurately. Researchers at Meta AI and NYU Langone Hospitals have developed an AI-based method to produce all necessary data 10 times faster.[148] Researchers from different universities in the US are working on new AI algorithms which allow predictions such as patients' pain levels or the mortality of heart disease patients from medical images or echocardiographic videos[149,150]. The Estonian company Healthy Networks OÜ has developed an AI-based stethoscope in combination with an app which allow users to monitor and detect cardiac or respiratory diseases[151].

Trend #20

Life sciences and healthcare in the metaverse (2026)

Innovation ★★★
Cyber Risk ★★☆

The metaverse can be considered the next version of the Internet, combining the benefits of AI, AR, virtual reality (VR) and increasing connectivity (e.g. based on 5G networks) to create online environments which are more immersive, experiential and interactive than today's. At the same time, the metaverse means the convergence of three major technological trends, all of which have the potential to impact life sciences and healthcare. These are, first, telepresence; second, digital twins; and third, blockchain and its ability to create a distributed Internet. Combined, the three trends could create entirely new opportunities and channels for drug discovery and healthcare delivery which have the potential to lower costs and significantly improve patient outcomes.[152,153,154] For HCPs and scientists, the metaverse could greatly change the way they work in the future. For example, surgeons could meet in a virtual operating room and collaborate on surgeries, assisted by other consultants and experts using VR/AR glasses such as HoloLens and Oculus from Microsoft Corporation and Meta Platforms Ireland Limited respectively[155]. Similarly, radiologists could collaborate on 3D medical images even though they are in different locations or countries.[156] Also researchers could benefit from the metaverse and better interact with each other. The VR-based visualisation software vLume developed by Lume VR Ltd., for example, allows scientists to interact in a VR environment.[157,158]

Commercial Organisation: Cyber risks and countermeasures

Trends for Commercial Organisation in the Life Sciences industry

- #11 Value based pricing
- #12 Wearable tech of the future
- #13 Novel digital therapies and health apps
- #14 Pharma-tech
- #15 AI-based chatbots
- #16 Omnichannel management
- #17 Novel personalised therapies
- #18 Smart body implants
- #19 AI-/ML-based medical diagnostic devices
- #20 Life sciences and healthcare in the metaverse

Key cyber risks

Health data theft/manipulation

Novel personalised therapies, implants, wearables, value-based pricing and omnichannel management all generate or process sensitive (health) data. If this data is not protected properly and data gets disclosed or manipulated, customers or patients will lose trust in life sciences companies. Furthermore, companies will likely be fined due to strict regulations and privacy laws.

Violation of regulation, e.g. patient data privacy

The secure storage and processing of sensitive personal patient data is subject to many different regulations and privacy laws around the world. Non-compliance can result in draconian fines and other legal consequences. This includes connected medical devices (e.g. wearables, smart body implants or AI/ML medical devices) and in some definitions even software and AI is considered as medical device.

Non-secure apps

In addition to the security of devices such as wearables, the security of the platforms and related health apps is key to protecting the health data of patients/customers. If security/privacy by design is not considered right from the beginning, vulnerabilities can allow hackers to steal health data.

Loss or manipulation of AI in therapies

AI algorithms could be sensitive intellectual property leading to a clear market differentiator. In the event of theft, this could have a significant financial impact. The manipulation of AI algorithms could lead to false diagnosis or therapies. In addition, mis-feeding/mis-training of AI algorithms could lead to false conclusions and research results.

Limited security of tech partner/supplier risk

Collaboration with and use of communication and other platforms from tech companies or other providers pose various 3rd-party risks, e.g. if an external platform/company is attacked, it is possible to access the data or further attack the entire network including the life sciences company.

Manipulation of smart devices (wearables, bots, implants, diagnostic devices)

If smart (and connected) devices such as wearables, bots, implants and diagnostic devices are affected by a cyber security attack, malfunction of the device can lead to the patient's injury or death, regardless of whether by chance or intended by the hacker. The loss of trust in these products can lead to market obstacles for the manufacturer.

Key cyber security strategies

Customer IAM

Mature processes for customer (e.g. patients, HCPs, public, other) identities and related access rights need to be implemented. This includes identity verification, user lifecycle management, access rights management & verification to ensure that only the right people have the right access at the right point in time.

Digital rights management for health data

Access to and use of health data needs sound controls during the whole lifecycle and across the boundaries of all involved parties. Proper digital rights management can protect the data itself including strong cryptographic measures to preserve the confidentiality and integrity of the sensitive health data.

Data governance & privacy

A sound data governance and privacy management system needs to be implemented. This includes but is not limited to data subject notification processes and the processes around data subject rights (information, rectification, erasure). Security control should be based on a privacy risk assessment. This has to consider legislation such as the GDPR and all other relevant national laws and regulations, e.g. regulations for smart medical devices such as the Guidance on Cybersecurity for Medical Devices of the EU, upcoming regulations from the FDA and the Medicines and Healthcare products Regulatory.

Secure software development

Secure software development procedures for novel digital therapies and health apps and related software should be implemented and applied. This includes continuous source code scans and security testing (e.g. based on DevSecOps). In addition, digital therapy and health app software quality should be enhanced by secure software training procedures.

3rd-party security

For the interaction and collaboration with pharma-tech, a 3rd-party security framework needs to be set up. This should include but is not limited to defined security controls and security maturity levels of the pharma-tech partners, contractual obligations, certification requirements (for products and 3rd parties) as well as third-party security audits and continuous monitoring.

Cloud security

The activity split between cloud provider and cloud user needs to be clearly defined. Cloud security controls should be implemented according to leading practices, and controls and monitoring of the cloud environment should be automated. Best practices in DevSecOps should be leveraged for changes to the applications and the related environment.

(Smart) product cyber security

Smart products such as wearables, implants or diagnostic devices with network connectivity – often including a direct Internet connection – can be accessed from anywhere and vulnerabilities exploited. Sound best practices for product cyber security need to be followed and independently tested. This includes considering the lifecycle of the product as well as the interaction with related services. Proper (customer) communication needs to be established in case of attacks or vulnerabilities.

Expert Interview: *Life sciences companies in particular must ensure a trusted relationship with customers and partners.*

Marko Vogel

Partner, Cyber Security, KPMG, Germany

Dear Marko, when it comes to cyber security, what are the most relevant cyber topics for your life sciences clients?

Our clients strive to establish a resilient organisation when it comes to cyber. As new threats – e.g. through the integration of IoT devices – are rapidly evolving, it is impossible to provide adequate cyber security by classical means. In addition, the ability to detect cyber-attacks and incidents as soon as they occur and the means to recover from such an incident and reduce the damage to a minimum are key to survival. Life sciences companies in particular must ensure that the trusted relationship with their partners and customers is not endangered and possible fines due to e.g. privacy data losses are kept to a minimum. To achieve this, we assist our customers in implementing holistic cyber security management that continuously adapts and improves. Furthermore, from a technology point of view, it is important to go beyond the standard IT infrastructure and include the production processes and customer-facing IoT device integration.

What are the key challenges for Chief Information Security Officers today?

More than ever, CISOs must be versatile and communicative leaders to fulfil their tasks. On the one hand, they must understand the business today and the implications of new life sciences trends on the cyber security stance of their organisations. They must be able to communicate the related risks to executive boards as well as business managers. On the other hand, they must be able to communicate these risks within their own organisations to the IT infrastructure, digital units and development groups to ensure appropriate measures are taken and necessary controls and monitoring are implemented – within their own organisation, but also in the supply chain and partner ecosystem. Additionally, they face the challenge of developing the necessary cyber security workforce in their organisations. Finding the right people and continuously training them to be a partner for the business and providing the right security services is becoming more and more the key factor for successful CISOs.

How does KPMG support life sciences companies regarding cyber security? Which proactive measures can be initiated together with the client?

In addition to the points mentioned above, we help our life sciences customers to ensure cyber security is well-managed in all phases – from prevention to detection, response and recovery in the event of an incident. Furthermore, we help incorporate security and privacy during the complete data lifecycle in order to take a security perspective for all new developments, including security/privacy by design.

Whether it is enhancing or extending identity and access management to cloud and customer or B2B scenarios, designing and implementing security monitoring to cover manufacturing IT scenarios as well or make the organisation more resilient starting with end-to-end backup services, developing service continuity plans and testing those up to full business continuity management, we as KPMG work shoulder to shoulder with our customers to provide the needed security services for the digital era.

KPMG offering for life sciences clients

Strategy & governance

Helping life sciences clients understand how best to align their cyber agenda with their dynamic business and compliance priorities

- Cyber maturity assessment (CMA)
- Cyber strategy/target operating model development
- Chief Information Security Officer metrics and reporting
- Information governance and privacy
- Third-party security risk management
- Business resilience
- Cyber in the audit

Transformation

Helping life sciences clients build and improve their programs and processes, supported by the right organisation and technology, to improve their cyber agenda

- Cyber Operating Model Build
- IAM
- Security GRC – Powered SecOps
- Technology integration
- Program delivery
- Powered IAM
- DLP

Cyber defence

Helping life sciences clients maintain their cyber agenda as their business and technology programs evolve by providing greater visibility and understanding of changing risks

- Technical assessments, including penetration tests, OT security Assessments, CBEST, TBEST
- Security operations and monitoring
- Security analytics
- Insider threat

Cyber response

Helping life sciences clients effectively and efficiently respond to cyber incidents and conduct forensic analysis and detailed investigations

- Incident response readiness and planning
- Digital investigations and remediation
- Threat intelligence
- KPMG Digital Responder
- Recovery support

Aligned with client business and technology priorities and compliance needs

Digital cyber security – Cloud | Mobile | Internet of Things | Operational Technology | Intelligent Automation | Blockchain | Managed Service

We have successfully delivered multiple cyber security projects for our life sciences clients

Case Study 1 (Privileged) Identity & Access Management Transformation for a Global Pharmaceutical company

Scope of work:

- Wrote an updated Policy for Privileged Access Management based on standards (e.g. NIST) and Industry Best Practices
- Designed technical configuration blueprints for Just-in-Time Access for cloud platforms and applications
- Performed and supported pilot implementation as well as User Acceptance Testing
- Supported a vendor evaluation for Identity Governance and Administration (IGA)
- Provided best practice insights into IAM processes, directives, and architecture
- Supported other workstreams, such as B2B Collaboration and Cloud Identity Governance

- Increased security level for administrative/ privileged accounts and permissions to counter the modern threat landscape
- High control and full transparency on the usage of privileged permissions and faster rollout of permissions
- Increased stability of the IAM infrastructure by relying on scalable, modern (cloud) technologies
- Increased user experience through clear and simple processes and faster onboarding of new (internal/external) employees with the right level of access

Case Study 2 OT Security scope for Manufacturing IT and Research area for a Global Pharmaceutical company

Scope of work:

- Defined the global manufacturing security policy for all production areas worldwide
- Designed, piloted and implemented global OT cyber security solutions to protect production sites and corresponding manufacturing IT
- Prepared rollout planning for all production sites
- Executed the rollout and rollout support by KPMG OT experts
- Prepared and executed Disaster Recovery training and tabletop exercises
- Prepared and executed Disaster Recovery plans

Benefits for the client:

- Improvement of the OT maturity level for all production sites worldwide
- Reduced risk of financial losses due to information security incidents
- Increased acceptance of OT security in manufacturing IT
- Standardisation of technical solutions and achievement of savings potential
- Increased response capabilities in the event of production downtime

Case Study 3 FDA blockchain pilot project to study blockchain's effectiveness for tracing prescription drugs and vaccines

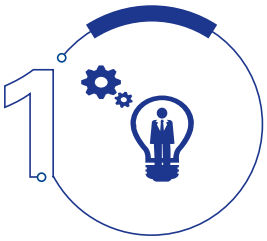
Scope of work:

- Together with Merck, IBM and Walmart and in close collaboration with the FDA's Drug Supply Chain Security Act (DSCSA) pilot program, KPMG has performed a pilot project to study blockchain's effectiveness for tracing prescription drugs and vaccines
- The pilot successfully connected a blockchain-based system from IBM with Merck's existing industry-standard system for serialication
- KPMG led the functional design of the pilot, including the process workflow, user interface development, defining configuration requirements and overall integration to demonstrate compliance with the DSCSA

Benefits for the client:

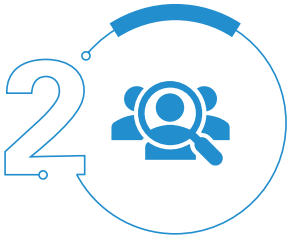
- Pilot participants were able to incorporate blockchain to determine product quality and origins of the product
- The pilot also showed how blockchain could potentially improve patient safety by reducing the time it takes to alert the supply chain of a product recall from a few days to a few seconds
- More information can be found here: https://info.kpmg.us/news-perspectives/industry-insights-research/fda-blockchain-pilot-successfully-completed.html

Eight life sciences cyber security considerations



Expanding the strategic life sciences security conversation

Change the conversation from cost and speed to effective security to help deliver enhanced value and experience for patients and HCPs.



Achieving the x-factor: Critical talent and skillsets

Transform the stance of life sciences companies' CISOs and their teams from cyber security enforcers to influencers.

Adapting life sciences security for the cloud

Enhance cloud security through automation — from deployment and monitoring to remediation.

Placing identity at the heart of zero trust

Put IAM and zero trust to work in today's hyperconnected life sciences workplace.

Exploiting life sciences security automation

Use smart deployment of security automation to help realise life sciences business value and gain a competitive advantage.

Protecting the privacy frontier

Move to a multidisciplinary approach to privacy risk management which embeds privacy and security by design in life sciences companies.

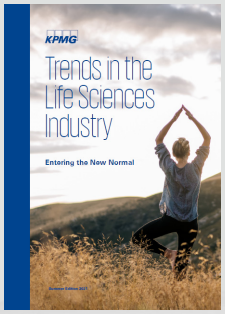
Securing beyond the boundaries

Transform life sciences supply chain security approaches — from manual and time-consuming to automated and collaborative.

Reframing the cyber resilience conversation

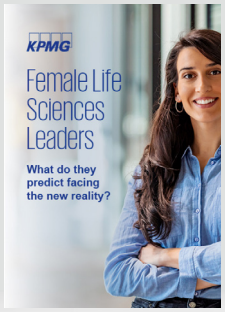
Broaden the ability to sustain life sciences operations, recover rapidly and mitigate the consequences for patients, HCPs and society as a whole when a cyber attack occurs.

KPMG's Life Sciences Library



Trends in the Life Sciences Industry

Deal Capsule: Transactions in Life Sciences

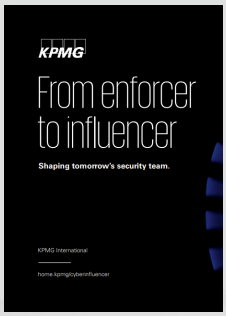


Female Life Sciences Leaders

Biopharma-ceuticals deal trends

"One-and-done" gene therapies

Cyber security considerations 2022



From enforcer to influencer

Securing a hyperconnected world

Privacy technology: What's next?

The changing shape of ransomware

The extended enterprise – securing the future

Human firewalling

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Methodology

Trend databases and media hubs were scanned for trends in pharma/life sciences as well as cyber security published in those databases between 26 June 2021 and 23 November 2021. This query resulted in a long list of 117 raw trends. Those raw trends were ranked and clustered and complemented with information from previous trend reports (KPMG Trends in the Life Sciences Industry Winter Edition 2020 and Summer Edition 2021). Eighteen trend clusters were selected based on their digital footprint and an important cyber risk/cyber security component (Note: Trends #7 and #8 were inserted during review cycles).

All trends were verified via primary research and enriched with further information through extensive desktop research and input from internal and external experts and classified into three categories (R&D, Manufacturing and Supply Chain, Commercial Organisation). Key cyber risks which as well as the corresponding key cyber security strategies were identified via expert insights. All trends were ranked according to their innovation and cyber security risk. The highest category of three stars was awarded to trends with groundbreaking innovations which do not yet exist. The stars for cyber security risks correlate with the number of risks identified for each trend (e.g. trend with one cyber risk = 1 star; trend with two cyber risks = 2 starts; trend with three or more cyber risks = 3 stars).

The trends listed in this publication represent a snapshot. It is important for life sciences companies to continue monitoring important trends.

Note: This trend report follows the 2020 Winter Edition and 2021 Summer Edition. Some of the current trends include information from previously published trends. The cluster numbers do not relate to the previous editions.

Companies and institutions in this report[1]

Company/Institution	Relevant trends
23andMe, Inc.	1
Abbott Laboratories	12
AbbVie Inc.	3
Advanced BioScience Laboratories Inc	7
Amblyotech, LLC	14
AMCM GmbH	10
Ancestry Ireland Unlimited Company	1
Atos SE	6
Autodesk, Inc.	10
Bayer AG	2, 3, 14,15
Bionaut Labs	5
BioNTech SE	8, 14, 17
Bitkom e.V.	6 (figure)
Boehringer Ingelheim Pharma GmbH & Co. KG	2, 6
Bristol-Myers Squibb Company	2
Canary Medical Inc.	18
Candel Therapeutics, Inc.	5
Catalent, Inc.	7
Charles River Laboratories	7
Concordia University	10
Continuus Pharmaceuticals	9
Dassault Systèmes UK Limited	4
Eli Lilly and Company	9
Enlace Health, Inc.	11
European Commission	9
European Medicines Agency	2
Evonik Industries AG	6
Genelink, S.L.	1
Genentech, Inc.	2, 17
German Federal Ministry of Health	13
Gilead Sciences, Inc.	11
GlaxoSmithKline plc	1,2
Global Life Sciences Solutions USA LLC	8
GNS Healthcare	4
Griffith University's School of Medicine	8
Grünenthal GmbH	16
Healthy Networks OÜ	19
Henkel AG & Co. KGaA	10
ICPerMed International Consortium	17
IKTOS	2
Insitro, Inc.	2
International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)	9
Johnson & Johnson GmbH	11
Koninklijke Philips N.V.	16
Lady Technologies Inc.	12
Lume VR Ltd.	20
Lonza Group AG	7
LunaPBC, Inc.	1
Lyfegen HealthTech AG	11
Massachusetts General Hospital Center	12
Massachusetts Institute of Technology (MIT)	9,10
Max-Planck-Gesellschaft	5
Merck KGaA	2, 3, 6, 10, 14
Merck Sharp & Dohme Corp.	16, 17
Meta AI	19
Meta Platforms Ireland Limited	20
Microsoft Corporation	14, 20
MIT Computer Science Artificial Intelligence Laboratory	12
Moderna, Inc.	17
Mojo Vision Inc.	18
MyHeritage Ltd.	1
mySugr GmbH	13, 14
National Human Genome Research Institute	1 (figure)
Nebula Genomics, Inc.	1
Nexa3D	10
Norgine GmbH	15
Novartis AG	2,11,14
Novo Nordisk Pharma GmbH	13, 15, 16
NYU Langone Hospitals	19
Ovy GmbH	12
Pear Therapeutics, Inc.	3
Personalized Medicine Coalition (PMC)	17
Pfizer Inc.	2, 3, 14 15
Recursion Pharmaceuticals Inc.	2
Roche Diabetes Care GmbH	13, 14
Roche Holding AG	2, 16
Saarland University	18
Sandoz International GmbH	16
Sanofi S.A.	6, 13, 14, 16
Self-Assembly Laboratory	10
Siemens AG	6
Stratasys Ltd.	10
Thermo Fisher Scientific Inc	7
U.S. Food and Drug Administration (FDA)	Introduction, 3, 4, 9, 18
United Rentals Australia Pty Limited	8
University of Zurich	5, 10
Unlearn.AI, Inc.	4
Viralgen	7
WALDNER Holding SE & Co. KG	8
WIN Consortium	17
Zenome.io Ltd	1
Zimmer Biomet Holdings, Inc.	18

1 Includes companies/institutions highlighted by name in the report. Further companies are indirectly included.

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