



# Where is life science heading in the future?

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# Introduction

This report is based on presentations made and discussions occurring during a conference at Engelsbergs bruk, 4-5 May 2017, which was arranged by the Stockholm Science City Foundation and the Axel and Margaret Ax:son Johnson Foundation. The conference aimed to bring together representatives of different organisations and fields of interest to discuss the present status and future development of the life sciences. Various aspects ranging from global political standpoints to new technologies and ways of working were covered. Several challenges and opportunities for countries wanting to take a leading role in the life sciences were highlighted, with the focus on the future role of Sweden. The report can be used as a strategic document for decision makers and organisations active in the life sciences. *Please note that this report attempts to summarise the presentations given by the speakers of the conference, it does not claim to provide a comprehensive description of all current trends or future possibilities in the field. Some of the statements may also present the personal views of the speakers.*

In brief, it is believed that healthcare in the future will be predictive, preventive, participatory and personalized. Technology is taking an increasing role in both academic research and healthcare, pushing a need for strategic investments and clever use of infrastructure and expertise. New types of cross-disciplinary collaborations are needed as science, healthcare and engineering converge and totally new opportunities arise in our connected and digitalised society. International collaboration and political openness are key in securing access to international talent, infrastructure, funding, knowledge and new therapies. Sweden has a good chance of maintaining a leading position in the life sciences. This requires effective utilization of national assets such as our information and communication technology (ICT) infrastructure and know-how, our non-hierarchical way of working, our national health registries and our access to funding.

## **The report is primarily based on presentations given by:**

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## **Photographs**

All photographs in the report were taken at the conference. Some depict individual participants: Emma von Witting on page five, Anders Lönnberg on page eight and Jens Nielsen on page 16. The photo on page 19, taken at Engelsbergs bruk, is of one of the old buildings next to the stream at the historic iron-works.

# 1. Technology is key

The life sciences have always been about deciphering biological complexity. With the tools at hand during the 20th century, biomedical scientists had to use a reductionist approach, where problems were studied one at a time. With the rapid development over recent decades of new technology and novel methods of analysing data, we are now – in the 21st century – in a position where complex integrated biological systems can be studied holistically. Large projects that have mapped the building blocks of life, such as the Human Genome Project and the Human Protein Atlas, have provided fundamental cornerstones for understanding life, but have also contributed to the progression of technology development.

New technology has given us faster, cheaper sequencing techniques, increased computational power, advances in big data analysis and higher resolution imaging capabilities. This has allowed an unprecedented increase in our understanding of human biology over the last few decades, and we can now for instance study the whole human genome in large samples of individuals. This has been hugely important for biological research as a whole, and a new field – systems biology – has arisen as a result. We are now approaching a tipping point where the systems approach has also begun to change medicine and clinical research, as well as healthcare systems.

Systems medicine and precision medicine are emerging fields that aim to individualise medical treatment. The digital revolution, which has provided increased connectivity and big data analytics, together with a systems medicine approach, enables fundamental changes to healthcare systems – moving from reactive systems that focused on diseases to a proactive system that focuses more on wellness and the ability to reverse disease progression, often at the very first signs of the disease. The roles of both medical professionals and patients will change in the future; patients will have the opportunity to take more control of their own health. Digital tools will drive patient empowerment and give them access to medical journals, self-care tools, online care consultations and peer communities. IT companies have seen the potential and are also entering the healthcare arena, offering for example advanced decision support for healthcare professionals and digital services to enable patients to manage chronic conditions at home. As the line between medicine and technology is blurring, tech giants are stepping in to support big data efforts like Allen Brain and Cell Atlas Institute (Microsoft, approx. 500 MUSD),<sup>1</sup> Biohub Cell Atlas (Facebook, approx. 600 MUSD)<sup>2</sup> and Project Baseline (Google, Verily), are also stepping in to support work with big data.<sup>3</sup>

## Glossary - The study of systems

*Systems biology* is the study of biological systems whose behaviour cannot be reduced to the linear sum of the functions of their parts. Systems biology often requires quantitative modelling methods borrowed from physics.

*Systems medicine* is an interdisciplinary field of study that looks at the systems of the human body as part of an integrated whole, incorporating biochemical, physiological and environmental interactions. Systems medicine draws on systems science and systems biology, and considers complex interactions within the human body in light of the patient's genomics, behaviour and surroundings.

*Precision medicine* is an emerging approach to disease treatment and prevention that considers individual variabilities in genes, the environment, and lifestyle for each person.

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<sup>1</sup> <http://www.brain-map.org>

<sup>2</sup> <https://czbiohub.org/projects/cell-atlas/>

<sup>3</sup> <https://www.projectbaseline.com>

In order to take advantage of these technological advances fully and advance the cause of the life sciences, it is necessary to invest wisely in technological infrastructure. It is important to find new ways of collaboration between organisations so that instruments and premises can be shared in cost-efficient ways. It is also essential to develop new organisational structures to foster cross-disciplinary collaboration (see next chapter).



## 2. Organisations need to adapt

The rapid development of technology, in combination with the systems approach to biology and medicine, requires new ways of working. For example, cross-disciplinary organisations would enable fruitful collaboration between biologists, engineers and computer scientists, allowing them to tackle scientific challenges together.

New organisational entities that have adopted this shift have emerged in different parts of the world. SciLifeLab in Sweden is one example. Another is the Koch Institute for Integrative Cancer Research at MIT, a national institute that has brought scientists and engineers together to battle cancer. With the joint mission of finding new ways of detecting, preventing and treating cancer, researchers are working together in cross-disciplinary teams to make maximal use of the latest technological and scientific advances. For example, the Koch Institute has become highly recognised for its work with nanomedicine, an emerging field that demands a range of expertise. Nanomedicine involves the study and development of engineered therapeutic agents for targeted delivery to cells, controlled or sustained release of pharmaceutical formulations, and nano-sized sensors and robots for diagnostic application. The Koch Institute is also handily located next to Kendall Square, a technology and innovation district in Cambridge, Massachusetts, that hosts companies like Biogen, Sanofi, Pfizer, Google and Microsoft. As a result, more than 50 biotechnology companies have been started from the Koch Institute since 2008. Many of these are in the nanomedicine area, with 11 prospective drugs in clinical trials.

This type of cross-disciplinary organisational development can also be seen in Asia. An increasing number of cross-institutional centres with international and national partners from academia, the private sector and research institutes have been established. For example, the Taiwan Cancer Centre is affiliated with the MD Anderson Cancer Center, the RIKEN Global Research Cluster and the Beijing National Laboratory for Molecular Sciences. There are also increasingly more theme-based programmes with a cross-disciplinary approach at universities; for example, these are appearing in the areas of genomics and “big biology”, aging and neurodegenerative diseases, robotics, medical devices and big data.

As basic research, medical research and clinical work become more interconnected, there is great potential to give patients early access to novel diagnostic methods and treatments. It is believed that this will have a dramatic impact on how clinical and scientific work is carried out and how the healthcare system will be structured in the future. Pioneers who bridge science and clinical practice and can bring new scientific tools into the clinical context will be key in this transformation, as will functioning regulatory systems and well managed organisations. The transformation is also putting new demands on the educational system to prepare students for working in cross-disciplinary environments.

*“Life science is a group effort. Collaboration between disciplines becomes increasingly important”*

-Dr. Anna Wedell

What hurdles must be overcome in these transformations? Those who are resistant to change and find it hard to adapt to new conditions will confront obvious challenges in the years to come if they aim to establish themselves in the forefront of the life sciences.

*“All paradigm changes are met with intense resistance, which means that all new ideas need new organizational structures”*

-Dr. Leroy Hood

# 3. Medicine and healthcare of the future

The increasing focus on systems biology has allowed unprecedented insight into the mechanisms of diseases, resulting in the discovery of novel drug targets to interfere with and slow or halt the process of disease. Thus, drugs are being developed to specifically interfere with the disease process rather than merely addressing disease symptoms. Today, the highest grossing drugs in the US are functional in only 4 to 25 percent of patients.<sup>4</sup> The new insights into disease mechanisms, the discovery of predictive biomarkers and access to fast sequencing equipment have combined to provide a better understanding of exactly who will benefit from a specific drug. This has led to the development of so-called precision (or personalised) medicine, an approach where treatment is tailored to fit individual patients.

## Three predictions for the future of medicine and healthcare

- Cross-disciplinary working environments will result in the development of new technology, generate new knowledge and deliver healthcare in better ways.
- The use of pioneering computational tools, big data analytics and digital connectivity tools will provide new insights into health and will empower patients.
- New tools for diagnostics, data analytics and prediction will facilitate the movement from reactive to proactive healthcare, enabling the prevention of diseases or the early reversal of certain conditions.

One of the main research areas in Asia involves the study of the Asian genotype and phenotype, and includes their impact on non-communicable diseases such as diabetes, cardiovascular disease and cancer. This is an area that has enormous impact on our understanding of disease susceptibility, prevention, diagnosis and treatment. The Genome Asia 100K project aims to sequence 100 000 genomes from various Asian ethnicities within three years, and to build a genomic variant database that will enable precision medicine applications.

Tools designed to gain insight into individual health situations will eventually lead to predictive and preventive healthcare. This will be achieved by encompassing data on genomes, proteomes, epigenomes, transcriptomes, phenomes, metabolomes and behaviour. Analysing the individual's genome and microbiome, combining this information with regular laboratory tests (blood, urine, saliva) and monitoring their lifestyle and physical activity will allow detection of the transition from wellness to early disease. This enables much earlier treatment than is possible today, and the potential to reverse the progression of disease. Today the costs of such analyses are high, providing a limiting factor for the transition to a more preventive healthcare process, but it is expected that costs will drop drastically during the coming decade. Technology development on the diagnostics side will be instrumental in bringing down costs. There is also a need for new, better biomarkers, especially blood biomarkers, which can be used to screen for early signs of disease.

From a healthcare provider perspective, three broad areas where development is currently very strong can be highlighted:

**Patient connectivity.** Digital connectivity tools will drive patient empowerment and give both patients and healthy individuals access to medical journals, self-care tools, online care consultations and peer communities.

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<sup>4</sup> Schork, NJ Nature. 2015 Apr 30; 520. Personalized medicine: Time for one-person trials.

**Healthcare delivery methods.** With today's specialised but fragmented care processes, it is difficult to coordinate healthcare around patients, especially those with chronic and/or multiple diseases. These challenges are being addressed by changing the work structure. For example, at At Karolinska University Hospital the work will be organised by multidisciplinary pathway management teams headed by a patient flow manager and the structure will be based on patient-centred rather than profession-centred pathways. There are currently large variations in the practice and hence the quality of healthcare between different regions and hospitals. The ever-increasing expenditure associated with healthcare is also resulting in a search for change in healthcare systems worldwide. In Scandinavia, as in other OECD countries, the cost of healthcare as a proportion of the GDP increases by 1 to 2 percent annually.

**Big data analytics and artificial intelligence.** New data analytical methods for extracting clinically relevant knowledge are needed. The use of artificial intelligence is expected to be instrumental in delivering decision support for medical professionals and patients, as well as for healthy individuals.



## 4. Drug development and access to new treatments

The business of drug development is undergoing a major transformation. The cost of bringing drugs based on novel active pharmaceutical substances to the market is extremely high (approximately \$US2.6 billion in 2016,<sup>5</sup> a 10-fold increase since 1975) and regulations for approval are becoming tougher. Today, only one in ten approved novel drugs ever becomes profitable. Hence, the industry is under pressure to make the drug development process more efficient and to adopt measures for smoother transitions between the pre-discovery, drug-discovery, clinical-trial and post-marketing stages. Synthetic small molecules remain important for the drug industry but there has been a shift towards development of biopharmaceuticals (also called biologics) during the last decade. This sector is expected to further increase in both industrial and clinical importance. In 2015, four of the five top selling drugs were biopharmaceuticals<sup>6</sup> and, in 2016, 7 of 22 novel drugs approved by the FDA were biopharmaceuticals<sup>7</sup>. This growth in the biopharmaceutical sector has put new demands on production skills and capabilities at pharma companies. Sweden is well positioned in this respect, with a long tradition of research, development and manufacturing of biopharmaceuticals, and several large investments in recent years from AstraZeneca and GE indicate that Sweden has a competitive edge.<sup>8</sup>

### Glossary

Biopharmaceuticals/biologics are medical products containing an active substance that is produced in, or extracted from, biological sources. This is in contrast to synthetic substances, which are usually referred to as small molecules because of their relatively small size. Biopharmaceuticals can, for example, contain proteins, DNA or cells.

Regulatory authorities are also changing the way drugs are approved so as to ease drug development and benefit patients in need of care. To encourage development of products for treatment of rare diseases, it is now possible to obtain a so-called orphan designation during the product development. If an orphan designation is applied, drug companies can obtain tax credits, reduced fees for approval and market exclusivity for several years once market approval has been granted. These measures were introduced to make development of drugs for small disease populations financially viable. This has had a measurable effect on the types of drugs developed. According to the FDA, orphan drugs are now the fastest growing drug group in development.<sup>9</sup> Adaptive licensing for market approval is also currently being tested in pilot projects. Approval for the drug is gained in stages, beginning with restricted populations and expanding to wider patient groups as evidence is gathered through real-life use and patients and assessment bodies are involved early in discussions of development plans. The concept is primarily being investigated for use in areas of high medical need where large clinical trials would unnecessarily expose patients who are unlikely to benefit from the treatment and data are difficult to collect in traditional ways. In the EU, the legal framework for this approach is already in place.

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<sup>5</sup> <https://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b>

<sup>6</sup> <https://www.pharmacompass.com/radio-compass-blog/top-drugs-by-sales-revenue-in-2015-who-sold-the-biggest-blockbuster-drugs> Top drugs by sales revenue in 2015: Who sold the biggest blockbuster drugs?". March 10, 2016.

<sup>7</sup> <https://www.fda.gov/drugs/developmentapprovalprocess/druginnovation/ucm483775.htm>

<sup>8</sup> [http://www.investstockholm.com/news/ge-healthcare-to-invest-\\$100m-in-uppsala-life-science-plant](http://www.investstockholm.com/news/ge-healthcare-to-invest-$100m-in-uppsala-life-science-plant)

<sup>9</sup> <http://www.accessdata.fda.gov/scripts/opdlisting/oopd>

Sweden has a history of leadership in clinical research. However, there has been a clear decline, of almost 40%, in the number of clinical trials carried out in Sweden over the last 20 years. Nonetheless, Sweden has several unique assets that could improve its position in this field. One is the national system of providing personal ID numbers to enable easy tracking of individuals. To lose track of a person participating in a clinical trial is expensive, so it is important to be able to follow the whereabouts of volunteers during trials. This is where the Swedish personal ID number comes in handy; it is almost always possible to find and contact participants during and after clinical trials carried out in Sweden. The many national registries are another asset; for instance, one is the world's largest twin registry which enables access to longitudinal, quality health data for monitoring and following up patients. Hence, Sweden has the potential for registry-based, randomised clinical trials in a way that few other countries can match. It is also relatively easy to recruit patients to clinical trials in Sweden because there is a high level of trust in medical science among patients.

### **Where will tomorrow's pharmaceuticals be developed and produced?**

According to Ulf Janzon at MSD, the key success factors for becoming a leading country in drug discovery and development are:

- Top class medical research.
- Top class healthcare with state of the art treatments.
- True patient involvement, with maintained trust to data access.
- Detailed monitoring of each patient, including patient-reported data.
- Use of ICT knowledge and infrastructure; in particular gaming and real-time data.
- Possibility of linking patient data to data from other registries and biobanks.
- Early access to new treatments, preferably the day after approval.
- A pharmaceutical industry that is prepared to share risks.
- Deep collaboration between academia, healthcare and industry.



# 5. Life sciences for sustainable energy conversion

Biology and the life sciences are not restricted to applications related to medicine and health, but are also used to address challenges related to our environment. Bio-based production may contribute to the establishment of a sustainable energy supply. The use of plant-based feedstocks allows for a closed carbon cycle and hence sustainable production of fuels and chemicals. Projections for the future state that biofuels will contribute significantly to the fuel market. The prediction is that the market will require *advanced biofuels* that can be used as diesel and jet fuels.

The ease of finding and burning fossil fuels has been driving economic growth during the last century all over the world, resulting in increased standards of living for most people on earth. However, this state has come at a price and we are now facing huge environmental challenges due to increased levels of carbon dioxide in the atmosphere, leading to increased global temperatures. The changed conditions for crop cultivation and increased sea levels will cause migration flows that we have probably never experienced before.

The current global energy use is estimated to be about 550 EJ, of which 80-90 percent is sourced from fossil fuels. Despite energy savings from the use of new technology, energy use is expected to grow to 860 EJ by 2050 as a result of population growth and increased energy demand in many countries. There is still a lot of oil accessible, but the cost of getting it is increasing.

There is a trend towards industry partnerships where competencies, risks, and capital investments are shared. For example, BP, BMW and DuPont have collaborated to develop production of isobutanol. Also, the flight industry is now investing in the field and jet biofuels are already in use, although in very small quantities so far. For example, United has a contract to purchase 57 million litres of renewable fuel in the period from 2016 to 2019 and several companies [Neste (Finland), AltAir Fuels (California) and Gevo (Minnesota)] are using different methods of producing the fuel.

Conventional biofuels (ethanol and biodiesel from plant oils) are expected to disappear and be replaced by second generation ethanol, advanced biodiesel and jet biofuels. So-called “cell factories” will be used to produce these. These are genetically modified cells that can be used in bio-refineries to convert different types of biomass to fuels and chemicals. Cell factories are also commonly used to produce food, beverages and pharmaceuticals. Genetic engineering can be used to optimise the cellular metabolism of cell factories for the intended use. For example, metabolic engineering has been used to increase insulin production in yeast 20-fold, and the production of fatty acids for making fuels has been increased >100-fold. Today, yeast is widely used in cell factory development but photosynthetic bacteria are also emerging as a very strong candidate for fuel production.

## **Opportunities and benefits of using cell factories to produce biofuels:**

- Reduction in greenhouse gas (GHG) emissions. Sugar cane biodiesel and cellulosic biodiesel are biofuels that result in low overall levels of GHG emissions.
- Clean technology. Research has shown that the use of biofuel in jet aircraft significantly reduces particle emission and, subsequently, global warming.
- Possibility of producing molecules with improved properties.

### **Barriers for widespread use of cell factories for production of biofuels:**

- It is costly and takes time to develop cell factories. Today it usually costs >50 million US dollars to produce a new cell factory and it usually takes 3-6 years and involves >100 person-years. New enabling technologies are needed to substantially reduce the time required to develop efficient cell factories for industrial production.
- It is difficult to obtain cost-competitive production. At yields of about 90 percent of the theoretical yield (as for current ethanol production), hydrocarbon production could be profitable, with a sugar price of about 0.10 USD/Kg without subsidy or 0.28 USD/Kg with subsidy. Hence, subsidies and mandates are required to get the biofuels industry to develop. Scale is important and therefore access to raw materials is also important. The distance from field to factory cannot be too long.
- The process is sensitive to volatile oil prices. Low oil prices will decrease the incentives for producing biofuels and high oil prices will increase the costs of bio-production, since oil-based fuels are currently used in the harvest of the biomass or crops used to produce the biofuels.

Climate and energy are high on the global political agenda. With the Paris agreement, countries around the world have put in place a roadmap for reducing consumption of fossil fuels to a minimum. In addition, climate laws have been introduced at a national level, in Sweden and elsewhere, to further drive the shift away from fossil fuels. Hence, there is a political intention and a sense of urgency that calls for new types of climate-neutral energy sources. There is a window of opportunity for those who invest in alternative fuels and Sweden has a chance to be an important player in the field of biofuels if the cards are played right. There are also synergies between the production of biofuels and the production of biopharmaceuticals, since they both rely on the same basic principles.



## 6. Global power shifts

Asia is a rising star in the academic world, leading a geographic shift in terms of scientific outcome, impact and research and development (R&D) spending. Currently, China is second only to the US when it comes to the number of articles published in peer-reviewed publications in the life sciences area, and Japan ranks seventh. While the Chinese output is very high (and rising), Singapore has the greatest impact among the Asian countries. The increasing impact of Asian research is also reflected in the climb of Asian institutions on global ranking lists: the National University of Singapore and the University of Tokyo ranked 20 and 22 on the QS Top Universities ranking in the Life Sciences and Medicines area in 2017.<sup>10</sup>

As a strategy to take the lead in the global “science and knowledge race”, Asian universities are eager to attract international talent. The number of courses given in English at the universities is increasing as part of their internationalisation strategy. Universities from other parts of the world are also encouraged to establish research, innovation and teaching campuses in Asia. The internationalisation of the Asian science community has also been facilitated by the fact that cultural barriers to living and working in Asia are on the decline.

The Asian biotech industry is also evolving, especially in China, thanks to efforts to speed up the drug approval process and the Thousand Talents programme. This 2008 government programme is targeting Chinese-born academics and workers who have trained overseas, encouraging them to return home with the promise of grants and tax breaks. This had led to an influx of talent at the same time as the Chinese Food and Drug Administration has made it faster and easier to move investigational medicines to the clinic. Together with a booming venture capital market, this has laid the foundation for a new generation of startups providing innovative biological treatments. Over recent years, pharma companies like Merck, Eli Lilly, Tesaro and Incyte have signed multimillion-dollar deals for drugs developed in China. However, in Singapore, despite an impressive increase in research quantity and quality, global pharma companies appear to be moving out.

The development seen in Asia stands in contrast with the current situation in many western countries where nationalism and protectionism may lead to increasing isolation and fewer opportunities for collaboration and exchange of knowledge. The fact that the UK is leaving the EU will undoubtedly have negative consequences for the life sciences community in Europe, and the Trump administration, with its protectionist agenda, anti-science statements and cuts in federal R&D spending, is of great concern.

Asia is also well placed when it comes to research that addresses globally important challenges. One focus area is the study of aging and neurodegenerative disease; the Asian focus on this area is partly driven by the fact that most rapidly aging populations are found in Asia. RIKEN in Japan, with its cross-institutional centres, is playing a vital role in these scientific advances. When Asia becomes a stronger market globally, diseases associated with Asia will also become more commercially relevant. Infection and immunity are also areas of great interest since large, economically diverse populations live in tropical environments where major tropical infections are found, and Asia is a potential source of pandemics such as influenza and emerging viruses. There is also an increasing interest in phytochemistry (the study of chemicals derived from plants) and traditional Chinese medicine, a field with a 2500-year documented history. The awarding of the 2015 Nobel Prize in physiology or medicine helped to increase the legitimacy of this field.

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<sup>10</sup> <https://www.topuniversities.com/university-rankings/world-university-rankings/2018>

## 7. The funding landscape is changing

Access to funding and the factors affecting the distribution of funding are essential for driving science forward. In Europe, the independent European Research Council (ERC) has been tremendously successful in this area. By distributing funding in Europe strictly based on scientific measures, without influence from any regional considerations, the European research community has been able to progress in many areas. However, there is concern about how the ERC will distribute their funding in the future because of Brexit. The UK has been one of the strongest advocates of the strictly scientific evaluation of research applications, and this might change when the UK leaves the EU, since some member states would like to get a larger share of the ERC budget.

The academic community in Europe depends heavily on funding from government agencies. There are only three large private funds in Europe that are active in the life sciences: the Wellcome Trust, the Knut and Alice Wallenberg Foundation (KAW) and the Novo Nordisk Foundation. This is in contrast to the situation in the US where philanthropists and private funds play a much bigger role. In 1970, the US government spent 2 percent of the GDP on basic research, but by 2015 that number had decreased to 0.76 percent. As a result, grants from the National Institutes of Health (NIH) have plummeted. Today only 14 percent of applications to the NIH are granted, compared to 30 percent in earlier years. On the other hand, philanthropic funds, private foundations and industry are taking a greater interest in funding academic research. As an example, 32 percent of the total research budget at the Koch Institute at MIT comes from philanthropic and private funders, and 20 percent of the total research funding at MIT comes from industrial sources. At the Koch Institute, only 53 percent of the total funding comes from federal agencies (compared to 73 percent ten years ago). Since industry has more interest in development rather than basic research, this has tended to cause a shift from basic to applied research in the US.

In Sweden, politicians are generally positive about science, technology and innovation, and there has been an increase in funding during the last 10 years. However, one third of academic researchers are not contributing to a single citation while one third, largely young researchers, are responsible for most of the output. This imbalance is a sign of an inefficient system where large resources are put into short-term research projects with limited or no impact. Sweden has dropped in scientific performance, especially in pre-clinical medicine, but increased funding is not the answer to this problem. Strong leadership, collaboration between universities and better allocation of the already available funding is the way forward. As an example, the KAW foundation focuses on finding young scientists and funding basic science in long-term projects, thus enabling greater individual freedom. When looking at the top 1 percentile of the most-cited articles globally during 2008-2015, the KAW-financed studies stand out as among the most highly cited.

The three large private funds in Europe are now collaborating to further boost European science and research by providing the best possible conditions for ground-breaking advances. In this work, the key is to identify strong individuals and teams and to take measures to ensure that equipment and infrastructure are used effectively.

In Asia, spending on R&D is increasing dramatically. South Korea and Japan spend well over the OECD average on R&D compared to the national GDP, and China is poised to outpace the US in 2019 in terms of total spending on R&D. While annual spending on biomedical R&D has been declining during the period from 2007 to 2012 in the US (-1.9 percent) and Europe (-0.4 percent), R&D expenditure has increased in several Asian countries, including China (+32.8 percent), South Korea (+11.4 percent), Singapore (+10.0 percent) and Japan (+5.7 percent) over the same period.<sup>11</sup>

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<sup>11</sup> [https://data.oecd.org/rd/gross-domestic-spending-on-r-d.htm#indicator-chart% of GDP](https://data.oecd.org/rd/gross-domestic-spending-on-r-d.htm#indicator-chart%20of%20GDP)

## 8. Political decisions with large impacts

Access to food is one of the global challenges; crops with increased tolerance to frost and drought as well as better pest resistance are needed to address current and especially future problems. However, as a result of the current political scene, Europe is not performing well in the area of plant biotechnology. The reason for the low R&D activity in this field in Europe is that cultivating genetically modified (GM) crops is banned in several European countries and only a limited number of GM crops have been approved for cultivation in the EU. As a result, almost no GM crops are cultivated in Europe while 60 percent of all crops in North America are GM. Europe is losing out in terms of the number of plant biotech patents to the US and Asia, meaning that the European agricultural industry is missing out on business opportunities and on taking a leading role in the future of crop development and food supply. However, the new Crispr-Cas technology may open the door for new opportunities in Europe, since plants is not classified as GM if single genes are replaced in the DNA, according to the Swedish Board of Agriculture, and this is possible using Crispr-Cas methods. On the other hand, Sweden holds a very strong position in the field of forest biotechnology. This field is booming worldwide due to the increasing demand for different types of biomaterials. Sweden is currently in the forefront of the field, not least via the tree-sequencing projects at Umeå Plant Centre and SciLifeLab.

With the UK leaving the EU and Donald Trump as president in the US, there is currently an uncertainty in how politics will affect science in the western world.

The new data protection laws in the EU also present challenges for the research community, the industry and the healthcare system.



# 9. Conclusions – challenges and opportunities

The future holds great possibilities for the life sciences and global health. Our understanding of life and biology is increasing at a rapid pace as a result of scientific and technological advances, leading to the development of new ways of treating medical conditions and the production of new biofuels, biomaterials and food. New opportunities to deliver therapeutics, monitor health and analyse health data are also being provided by increased cross-disciplinary collaborations. Sweden is at the top of several innovation scoreboards and holds a strong position in the life sciences. However, there are challenges that need to be addressed if Sweden wants to stay in the forefront of the life science fields:

**Technological equipment and infrastructure.** As technology becomes increasingly important but also more advanced and expensive, it is important to secure access to both equipment and technical know-how. Hence, it is essential to plan and coordinate infrastructure investments carefully to support the scientific and clinical communities. Collaborations like that seen at SciLifeLab, where equipment, premises and expertise are shared between organisations, will be increasingly important if Sweden is to stay ahead in the future. The infrastructure investments (both national and European where Sweden is involved) need to be carefully planned and should be focused on strong Swedish research areas. The European Spallation Source (ESS) in Lund will probably become very expensive for Sweden and will drain resources from other research areas.

Sweden holds a strong position in the research, development and production of biopharmaceuticals and there have been recent investments in the sector from the government, the KAW foundation and companies (AstraZeneca and GE). This sector is related to the sustainable bio-based production of biofuels using cell factories. Both the biopharmaceutical and the biofuel sectors may benefit from increased collaboration and the use of common resources and infrastructure (as seen, for example, at SciLifeLab and the division of Systems and Synthetic Biology at Chalmers).

**Leadership and collaborative organisations.** Cross-disciplinary collaborations are part of the recipe for the future of the life sciences. As biology, engineering and computer science continue to converge, new ways of working together are needed. It is also necessary to prepare students for collaborative and cross-disciplinary work. Because paradigm changes are often met with resistance, new ideas often require new organisational structures such as institutes and centres to be set up. Here, strong leadership that is open to change and based on a sound knowledge of future opportunities is important. It is also important to form trustworthy models for collaboration between industry, healthcare providers and academia.

In Sweden, many of the prerequisites for this type of cross-disciplinary collaboration are already in place. Non-hierarchical collaboration is well rooted in Swedish culture. There is also a high degree of trust in Swedish society and a well organised healthcare system that can provide the stability needed for transformation in the health sector. It also helps that Swedes in general are well educated and have a positive attitude towards science, which makes it relatively easy for them to accept changes based on scientific and technological advances. However, there are issues that need to be addressed before the process of transformation can be scaled up. Going from partly isolated projects lead by committed individuals to increased collaboration in academic and clinical organisations needs strong leadership.

Another issue is the lack of a national strategy in Sweden for harmonising the change in the way research and clinical work is carried out. This will be more important as the areas become more intertwined and dependent on each other. It is also important to put in place a plan for how the diagnostic revolution can lead to a therapeutic revolution.

**ICT knowledge and infrastructure.** As our increasingly connected society provides totally new opportunities for the life sciences and healthcare systems, it is important to take full advantage of digital expertise and infrastructure. Sweden, and Stockholm in particular, has all the prerequisites for taking a leading role, thanks to our strong life science and ICT communities, together with extensive health data registries, biobanks and digital connectivity infrastructure. However, there is fierce competition in attracting good computer scientists and programmers, and the education system has an important role to play in this area. Healthcare providers need to develop a willingness to test and use new technology and to change their ways of working. Stronger incentives from the political arena may also be needed.

**Patient involvement.** In order to grasp the opportunities offered by our digital connectivity to improve healthcare and clinical trials, it is important to really understand how to achieve true patient involvement. This requires maintained trust in the data gathering and handling processes and the introduction of methods of linking patient data, including self-reported data, with data from other registries and biobanks.

**Allocation of research funding.** The fact that one third of the academic researchers in Sweden are not contributing to a single citation indicates that a proportion of the extensive resources that are put into research projects has limited impact. Short-term project financing and the relative difficulty young researchers have in obtaining sufficient funding partially explain this problem.

**Political openness and international presence.** To stay relevant in the life sciences arena, international collaborations are key. Establishing a presence abroad is one way of facilitating collaboration and promoting bilateral mobility and knowledge exchange. There is room for reform in this area, so that Swedish tax money can finance activities in Swedish universities situated outside Sweden, something that is not possible today. To secure access to international talent, infrastructure, funding and knowledge, Sweden also needs to stay within international organisations and structures for collaboration. With regard to the global powershifts described earlier in this report, Asia is an important region for Swedish collaboration.

**Access to new therapies.** Biopharmaceuticals are in many cases very expensive, and this raises concerns about future access to new therapeutics since the healthcare system is under pressure to maintain its current cost level. Industry and healthcare need to establish strategies and guidelines for precision medicine so that only those patients who can benefit from treatment get access to the expensive therapeutics. Regulating authorities also need to continue the international regulatory harmonisation process so that new therapeutics are made available for patients worldwide, as soon as possible. There are concerns regarding European collaboration since the UK is about to leave the EU, with unknown consequences for joint work by the European Medicines Agency, in which the British Medicines and Healthcare Products Regulatory Agency is currently a strong partner. Increasing the number of clinical trials in Sweden is one way of achieving early access to novel therapies, since this makes the healthcare system better equipped for receiving and trying out new therapies. This also increases access to knowledge and creates opportunities for scientific discoveries and academic research within Swedish healthcare organisations.

**Regulations that balance safety and integrity with innovation.** Regulations that are too rigid will inhibit innovation, although personal safety must always be secured. The regulations differ widely in the clinical setting compared to the basic research laboratory. This will be challenging when the two environments become more intertwined, especially if the time between an invention and patient benefit from a new therapy is to decrease. The new data protection rules in the EU will also present new challenges for research involving personal health data. There is no simple solution to these challenges, but they will certainly influence the speed with which we approach the future scenarios of health and medicine outlined in this report.

