

Synthetic & Engineering Biology: A joint opportunity for the UK and Switzerland

Health and Life Sciences











Contents

Exec	utive Summary	3
Sumi	nary of Recommendations	4
Back	ground	5
	Synthetic & Engineering Biology for Health and Life Sciences	6
	Synthetic & Engineering Biology in Switzerland	7
	Synthetic & Engineering Biology in the UK	7
Discı	ssion topics, reflections and recommendations	8
	Discussion topic 1: Collaborative and pro-innovation cross-country regulations to accelerate innovation	8
	Discussion topic 2: Building a skilled workforce to drive synthetic & engineering biology solutions for health and life sciences	.10
	Discussion topic 3: Bioprocessing and scale up	.12
	Discussion topic 4: The role of Al in synthetic & engineering biology for health and life sciences	.14
	Discussion topic 5: Barriers to commercialisation	.16
Conc	luding remarks	18
	Annex 1: Summit delegates	.19

This report was led by Kerstin Kinkelin (University of Bristol, UoB), with support from Kathleen Sedgley (UoB), Linda Bedenik, Maddie Cass and Rosie Lindup (BioIndustry Association, BIA), Anike Te (Lucideon) and Natalie Thomas (Swiss Business Hub UK). Delegates who participated in the roundtable discussions informing this report are listed in Annex 1.

For more information on this report, or to share feedback, please contact Kerstin Kinkelin at k.kinkelin@bristol.ac.uk

Executive Summary

The British-Swiss SynBio Summit programme is a collaborative cross-sector venture across the UK and Switzerland, and organised by the <u>University of Bristol</u>, the <u>Swiss Business Hub UK</u>, the UK BioIndustry Association (BIA) and Lucideon.

Building on the success of the <u>inaugural Summit in 2024</u>, and advances in areas such as Cell & Gene Therapy, RNA therapeutics and biologics, the 2025 Summit, hosted by the Swiss Ambassador H.E. Dominique Paravicini at his Residence, convened diverse voices across academia, life science and pharmaceutical industries, Government and policy makers to transverse geopolitical borders and foster dialogue on advancing synthetic & engineering biology for health and life sciences. Through roundtable discussions, the Summit explored challenges and solutions in five key areas: collaborative and pro-innovation cross-country regulations, building a skilled workforce, bioprocessing and scale-up, the role of Al, and barriers to commercialisation.

The initiative forms part of broader efforts to strengthen UK-Swiss bilateral cooperation in "deep science" and "deep tech" (including health and life sciences), following the Memorandum of Understanding signed in November 2022 and renewed in November 2024.

The UK and Switzerland share strong foundations in health and life sciences and significant opportunities to deepen bilateral collaboration across regulation, workforce development, manufacturing, Al, and commercialisation.

Building on existing regulatory frameworks, both nations have mechanisms to enable flexible, risk-based approaches and cross-border collaboration. However, differences in national laws and reform timelines present ongoing challenges. Greater alignment, particularly in emerging technology areas, could enhance innovation and expand patient access across both markets.

Workforce development remains a critical enabler for the sector. Skills gaps in bioprocessing, regulatory science, and data-driven manufacturing constrain growth, while Switzerland's mature vocational system offers lessons for the UK's developing industrial strategy. Strengthening university-industry partnerships will be key to equipping the next generation of talent with the practical expertise needed to support emerging technologies.

Bioprocessing and manufacturing face increasing molecular complexity and funding constraints. Joint UK-Swiss initiatives, including regulatory harmonisation and collaborative clinical trials, could expand research capacity and access to larger patient populations. Al integration offers transformative potential but requires international cooperation on standards for data governance and dual-use oversight, alongside workforce upskilling.

Commercialisation remains limited by lack of scale-up capital to grow companies in Europe. Treating science as a strategic investment, expanding applied R&D funding, and strengthening infrastructure are essential to translate research excellence into tangible health and economic impact.

The Summit highlighted the UK and Switzerland's complementary strengths, sectoral challenges, and the opportunities for cross-border collaboration to drive innovation in synthetic & engineering biology for health and life sciences.

Summary of Recommendations

To address identified challenges affecting the development and uptake of synthetic & engineering biology technologies for health and life sciences, we propose the following recommendations for the UK and Swiss governments, industry, educators and the entire innovation ecosystem.

Our recommendations for the **UK and Swiss governments** are:

- Deepen UK-Swiss regulatory collaboration to harmonise frameworks, co-develop guidance for emerging technologies, and support joint training to strengthen regulatory expertise.
- Enable flexible, risk-proportionate regulation by expanding innovative pathways and ensuring early, informal engagement between regulators and innovators.
- Invest in talent and capacity expand vocational and regional training and distribute health and life sciences ecosystems beyond existing super-clusters.
- Strengthen biomanufacturing and scale-up infrastructure, improving funding access for SMEs and supporting initiatives such as joint clinical trials.
- Enhance global cooperation, fostering shared standards, data management frameworks, and responsible Al oversight.
- Promote biosecurity and dual-use awareness across the ecosystem through clear definitions, oversight mechanisms, and cross-sector training.
- Provide sustained funding for applied R&D, scale-up facilities, and early-stage innovation.

Our recommendations for **industry** are:

- Engage early with regulators to accelerate development, gain clarity, and de-risk innovation pathways.
- Leverage technological and distributed manufacturing innovations to build a more agile, resilient, and globally connected health and life sciences system.
- Harness machine learning and data analytics to unlock process efficiencies and drive next-generation bioprocess innovation from underutilised industrial datasets.

Our recommendations for **educators** are:

- Co-design curricula with industry to equip learners with the practical and technical skills demanded by the health and life sciences sector.
- Integrate applied Al training and literacy across education programmes to strengthen digital capability among students and educators.
- Align academic incentives with innovation and impact, recognising translational research and commercial engagement alongside teaching and publication.

Our recommendations for the entire innovation ecosystem are:

- Invest in regulator and researcher capability, expanding training, secondments, and cross-sector learning to strengthen expertise in emerging technologies.
- Promote open, early collaboration between regulators and innovators, to accelerate translation and ensure responsive, risk-proportionate regulation.
- Align education and industry needs through initiatives such as Professors of Practice, translational institutes, and industry-led teaching partnerships.
- Enhance manufacturing agility and supply chain resilience by developing flexible production systems, improving data standardisation, and strengthening cross-border collaboration.
- Embed responsible innovation and ethical oversight across research and funding processes, fostering shared accountability and critical engagement in the use of Al and advanced technologies.

Background

The Synthetic & Engineering Biology British-Swiss Summit is a collaborative venture between academic and industry leaders across the UK and Switzerland, organised by the <u>University of Bristol</u>, the <u>Swiss Business Hub UK</u>, the <u>UK BioIndustry Association (BIA)</u> and <u>Lucideon</u>.

Designed to bring together diverse voices, the Synthetic & Engineering Biology British-Swiss Summit aimed to transverse geopolitical borders and foster dialogue on advancing synthetic & engineering biology technologies – a field of strategic importance for both the UK and Switzerland – and ultimately identify routes to impact.

More than 40 representatives from British and Swiss universities, SMEs, startups, corporate organisations, Government, Parliament, funding bodies and policy makers joined roundtable discussions at the Embassy of Switzerland in London in October 2025, to explore challenges and solutions affecting the development and uptake of synthetic & engineering biology technologies for health and life sciences. Parallel roundtable discussions were held focusing on five topics:

- 1. Collaborative and pro-innovation cross-country regulations to accelerate innovation
- 2. Building a skilled workforce to drive synthetic & engineering biology solutions for health and life sciences
- 3. Bioprocessing and scale up
- 4. The role of Al in synthetic & engineering biology for health and life sciences
- 5. Barriers to commercialisation

The resulting recommendations align with the <u>Memorandum of Understanding</u> signed in November 2022 and renewed in November 2024 between the two countries, which aims to "encourage cooperation in 'deep science' and 'deep tech' (including health and life sciences), as well as commercialisation through innovation, and policy and diplomacy in science and innovation."

Synthetic & Engineering Biology for Health and Life Sciences

Synthetic & engineering biology is a powerful enabling technology that underpins much of modern biotechnology today.

Synthetic & engineering biology is the "application of engineering principles to biological systems in ways that allow us to harness and control biology in predictable and useful ways. For example, to create novel products and processes that are safer, cleaner and more efficient." It includes both 'top down' approaches such as the manipulation of nucleic acids (DNA/RNA), and 'bottom up' approaches such as *de novo* protein and biomolecular or biomaterial design to build biological or bio-inspired products with new or improved functions.

The universal nature of the synthetic & engineering biology toolkit means that it can be applied across many sectors, including energy, environment, food production, chemicals, materials and healthcare.

The health and life sciences sector has been an early adopter of synthetic & engineering biology technologies, which have enabled transformative approaches including for example:

- Integration of heterologous pathways into designer cells to efficiently produce therapeutic agents, such as human insulin production in engineered bacteria
- Synthetic mRNA vaccines, such as those developed for COVID-19, first approved for use in the UK
- Personalised medicine through genetic and cell engineering, such as CAR-T cell therapy for cancer treatment
- Biosensors for real-time disease diagnostics, such as wearable glucose biosensors for diabetes

Significant obstacles must still be addressed so that synthetic & engineering biology solutions can be translated out of the lab at scale in order to deliver meaningful impact. For example, synthetic & engineering biology is unlocking new modalities for treatment, which results in uncertainty from a regulatory perspective. Regulators and innovators are grappling with the challenge of demonstrating safety, efficacy, and quality for products that do not fit neatly into existing regulatory categories. Building confidence in the use of complex technologies takes time, and regulators and policymakers are challenged to create an environment conducive to supporting existing and emerging innovative companies in this space and enabling the far-reaching uptake of their products by healthcare providers and patients.

Developing synthetic & engineering biology innovations from the lab bench to commercial scale manufacturing poses myriad technical challenges. Innovators need to grapple with the variability of biological systems, a lack of industry standards, and the challenge of scaling up a bioprocess.

These technical and regulatory hurdles mean that commercialising an innovation is a lengthy and expensive process, and as a result many companies struggle to land sufficient investment to realise their vision. In addition, synthetic & engineering biology remains a space where deep expertise and higher risk tolerance are in demand amongst investors.

Through roundtable discussions, we aim to explore challenges and solutions affecting synthetic & engineering biology applications in health and life sciences. The outcome is to take these recommendations forward to both the UK and Swiss institutions, key stakeholders and governments who can influence the progress of this field.

Synthetic & Engineering Biology in Switzerland

Switzerland is dedicated to research and innovation. According to the <u>Federal Act on the Promotion of Research and Innovation</u>, the Confederation aims to encourage scientific research, science-based innovation, support the analysis and exploitation of research results, ensure cooperation between research bodies and the economical and effective use of federal funding for scientific research and science-based innovation. Synthetic biology falls under this type of research and innovation.

Synthetic biology is being developed by leading academic institutions such as the ETH and EPFL. A national network "Molecular Systems Engineering" ensures that the main stakeholders are connected and coordinated. The Swiss Innovation Parks across the country support research and development, including synthetic biology focused startups and SMEs.

Switzerland's healthcare regulatory framework is robust, internationally aligned, and highly focused on ensuring safety and efficacy while enabling innovation. As a key player in global pharmaceutical frameworks in various international platforms such as ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use), ACCESS
ACCESS
Consortium etc., the Swiss Agency for Therapeutic Products, Swissmedic, actively participates in international harmonisation efforts, thereby helping to maintain high regulatory standards while promoting and facilitating the drug development and approval processes both domestically and internationally.

The <u>Swissmedic Innovation Office</u>, launched in late 2022, supports early-stage innovators – especially small companies, start-ups, and research groups – by fostering close dialogue and reducing regulatory barriers to bring innovative medicines to patients faster. During its pilot phase through 2024, the office focused on advanced therapeutic medicinal products (ATMP), leveraging a small expert team to guide stakeholders in cell and gene therapies, siRNA, and related fields.

Synthetic & Engineering Biology in the UK

Note: While most nations use the term "synthetic biology," the UK uses "engineering biology" in all policy frameworks and governmental initiatives.

In recent years, the UK's burgeoning engineering biology sector has benefited from cross-party support. The current Government positions engineering biology as a frontier technology in the UK's <u>Digital and Technologies Sector Plan</u>, due in part to its potential to deliver <u>2.32% real GDP growth by 2035</u>. The <u>UK's 2025 Industrial Strategy</u> surfaced engineering biology as an enabling platform technology, further playing a critical role in the ambitions of the Life Sciences Sector Plan.

Regulatory reform has been prioritised as a key economic growth driver. The Engineering Biology Regulators Network (EBRN) was established in 2023, bringing together the 12 relevant regulators across the UK. In 2024, the Regulatory Innovation Office (RIO) was created to reduce regulatory burden and accelerate technology access. The UK pioneered regulatory sandboxes for testing new products under regulatory supervision, with the first engineering biology sandbox launched in March 2025, focused on cell-cultivated products. Additional sandbox funding has since been announced, providing UK regulators with up to £3 million to work with innovators on regulatory challenges. The UK partnership between Innovate UK, the Medicines and Healthcare products Regulatory Agency (MHRA), Office for Life Sciences and the Medical Research Council (MRC) have also established seven Centres of Excellence for Regulatory Science and Innovation to help drive advancements in health and life sciences.

Discussion topics, reflections and recommendations

Discussion topic 1: Collaborative and pro-innovation cross-country regulations to accelerate innovation

International cooperation brings benefits to patients, researchers, and industries by improving access to healthcare, accelerating the development of new treatments, and promoting economic growth in the sector. To enable these benefits, international harmonisation of health and life sciences regulations is critical, streamlining research, reducing barriers to trade, and accelerating the development and distribution of safe and effective medical products globally.

How can we learn from the regulatory ecosystems across the two nations and existing mechanisms supporting regulatory cooperation such as the <u>ACCESS Consortium</u>, identifying translatable examples of best practice, and surfacing opportunities for further harmonisation and collaboration?

What are the risks and opportunities presented by ongoing legislative reform, including for example the current revision of the <u>Swiss Therapeutic Products Act</u> and the <u>UK's clinical trial</u> regulations reform? And how can we best support entirely novel innovations that don't easily map onto existing frameworks?

Reflections:

- Switzerland has a broader ATMP definition than the UK/EU, which allows Swissmedic
 to apply a flexible, risk-based approach that accommodates diverse new modalities
 (e.g., oligonucleotides), though better communication is needed to help companies
 understand this advantage.
- Swissmedic and MHRA collaborate and share confidential information through the <u>ACCESS Consortium</u>, allowing seamless alignment on regulatory requirements and provision of joint scientific advice.

- Swissmedic values strong collaboration within the <u>ACCESS Consortium</u> with all members, including MHRA, TGA (Australia), Health Canada and HSA (Singapore).
- Regulatory harmonisation would help companies navigate markets more easily, but
 differing national laws and slow reforms such as varying ATMP definitions pose
 major challenges. The success of global collaborations like COVID-19 vaccines and
 Project Orbis shows the potential benefits, and aligning UK-Swiss regulations in
 emerging areas like ATMPs could make both markets more attractive for innovation.
- UK and Switzerland have the shared challenge of regulatory divergence from the large local markets (the EU) which along with US markets are prioritised by most companies.
- The MHRA is continuing to develop its capacity for deep regulatory expertise and experience, which will help to manage emerging synthetic & engineering biology innovations that challenge existing frameworks.
- The UK tends to adopt a policy driven approach, identifying strategic areas for developing an advantage in these areas. In contrast, Swissmedic adopts a comprehensive approach, developing expertise across all areas in which it receives applications.

Recommendations:

Government:

UK regulators should be encouraged to offer more flexible, risk-proportionate pathways to support access to innovative therapies – expanding the use of models like the <u>Innovative Licensing and</u>
Access Pathway (ILAP) and national conditional marketing authorisation (CMA) scheme.

Swiss and UK regulators should continue close collaboration to provide consistency and harmonisation across borders.

Case study: <u>Project Orbis</u> serves as a key example of how coordinated international review can shorten timelines for novel products to reach patients. Under Project Orbis, the MHRA, Swissmedic and six other international regulators participate in collaborative assessments of cancer medicines while retaining full national authority over final decisions. The arrangement has enabled <u>faster Swiss</u> and UK access to treatments such as <u>osimertinib</u>, demonstrating that structured information-sharing and synchronised evaluation can reduce duplication without lowering standards.

UK and Swiss regulators to jointly identify rapidly evolving technologies to enable cross-national training and development for regulators to strengthen regulatory expertise.

Regulators to continue to develop informal routes for innovators to access advice at early stages.

Industry:

Companies to proactively approach regulators at an early stage.

The entire innovation ecosystem:

Provide opportunities for regulator training and development in rapidly evolving technologies, such as industry secondments, shadowing and conference attendance.

Strengthen efforts to maintain an open dialogue between regulators and innovators, and enable early informal discussions and advice.

Case study: Companies developing engineered microbial therapeutics (EMTs) have been working with the RIO and the BIA to engage the MHRA and Defra (Department for Environment, Food & Rural Affairs) on the regulatory questions facing this emerging class of therapies. Due to the novelty of the approach, companies developing EMTs face uncertainty on the pathway to market authorisation, both in the UK and globally.

By bringing together a cohort of EMT developers, RIO and the BIA have helped structure dialogue with the relevant regulators so shared challenges can be examined collectively. Early discussions are beginning to clarify issues such as the lack of relevant guidance, uncertainty as to how EMTs fit into the ATMP framework, and on the classification of genetically modified organisms. The group continues to meet, with further sessions planned with the MHRA to explore specific technical and regulatory questions. This collaborative approach demonstrates how early engagement can support a more predictable regulatory environment for synthetic & engineering biology SMEs, and support innovative therapies to reach the clinic.

Discussion topic 2: Building a skilled workforce to drive synthetic & engineering biology solutions for health and life sciences

Building a skilled workforce is critical for realising the full potential of synthetic & engineering biology with regards to medicines and advanced therapies manufacturing. Translating breakthroughs from the laboratory into safe, effective, and commercially viable products demands professionals who can integrate biological insight with engineering principles, digital tools, and rigorous quality standards.

In health and life sciences, this includes developing expertise in process design, optimisation, scale-up and regulatory compliance for production of small molecules, biologics, and complex drug delivery systems. Specialists must also navigate the unique challenges of personalised products for advanced therapies, variable starting materials, and highly controlled and regulated manufacturing environments. We must also foster an understanding of patient-specific manufacturing considerations, cold chain logistics, and the evolving standards for ATMPs.

As Al and advanced automation reshape the manufacturing landscape, aspiring bioscience professionals will require not only deep technical knowledge but also adaptive skills in systems thinking, cross-sector collaboration, and data-driven decision-making.

How can we collaborate across academia, industry, and regulatory bodies to deliver targeted education and training for these needs, and where do the most urgent skills gaps lie?

Reflections:

- With the rapid advancement of synthetic & engineering biology technologies for health and life sciences, the workforce must meet increasingly complex demands. Current skills gaps cover areas such as bioprocessing, scale-up & manufacturing; Regulatory, GMP (Good Manufacturing Practice), Quality, Compliance & Risk Assessment; and Data, Automation and Digital.
- Identifying skill shortfalls through foresighting remains a challenge due to the rapidly
 evolving nature of synthetic & engineering biology technologies. Analytical reports such
 as <u>Life Sciences 2035</u>: <u>Developing the Skills for Future Growth</u> provide crucial insights
 to enhance understanding of future business needs and skills requirements.
- Applied universities in the UK and Switzerland have strong links with industry through entrepreneurial curricula and industry-focused teaching. Conversely, traditional universities face challenges in embedding industrial experience into academic programmes – placement years are inconsistently supported, and companies show hesitancy in engaging with longer term collaborations such as PhD projects.
- A strong local ecosystem and supporting infrastructure are essential to sustain
 workforce competitiveness. Access to surrounding education clusters and a large talent
 pool within industrial clusters are crucial for talent attraction and retention. Employers
 based in more isolated locations struggle to compete for talent with those based in
 thriving ecosystems such as Basel (CH) and the 'Golden Triangle' of London, Oxford,
 Cambridge (UK).
- Switzerland's vocational training system remains a cornerstone of its industrial success, particularly in bioprocessing and GMP operations. Whilst the UK has prioritised investing in and expanding the vocational training system as part of the latest <u>Modern Industrial</u> <u>Strategy</u>, it is currently still in its infancy and does not yet sufficiently address skills gaps.
- SMEs and startups dominate the synthetic & engineering biology sector and are
 therefore primarily affected by the skills gap. Yet it is those organisations that struggle
 most with investing in upskilling, and engaging with curriculum development, due
 to financial and time constraints. Foremost in the UK, SMEs and startups are facing
 significant administrative and financial barriers to access apprenticeships.
- Early engagement is key to building the workforce of the future, to raise awareness of diversity of career pathways in the synthetic & engineering biology sector.

Case study: Science Creates Outreach (Bristol, UK) is a charity with a mission to educate and empower young people to engage with STEM and entrepreneurship, encouraging innovation and problem-solving, and equipping them with the knowledge and confidence to change the world. By welcoming young people to The Learning Lab, located in the heart of a working Deep Tech ecosystem, learners are surrounded by scientists and engineers of different ages, genders and backgrounds. Here, they are shown that leading STEM innovation is done by people just like them.

Recommendations:

Government:

Support ecosystems in geographically diverse locations to distribute talent pools and avoid concentration of industry and talent in a small number of super-clusters.

For the UK to learn from Switzerland's well established vocational training programme, e.g. through study visits for UK education leaders, such as those organised by the <u>Gatsby Charitable</u> Foundation.

Industry:

Engage with educators to provide insights on business needs with respect to skills and developing talent.

Educators:

Work closer with industry in developing curricula that provide learners with industry-relevant skills, such as the University of Bristol's 'PhD for the Future' roundtables.

The entire innovation ecosystem:

Expand initiatives such as <u>Professors of Practice</u> (ETH), industry guest lectures, and translational institutes such as the <u>Swiss Institute for Translational and Entrepreneurial Medicine (sitem-insel)</u>, to enhance alignment between university education and industry needs.

Discussion topic 3: Bioprocessing and scale up

Synthetic & engineering biology is transforming manufacturing of medicines and advanced therapies. It enables faster, more efficient production of biologics and vaccines through process intensification, closed systems, and automation, as well as supporting scalable, reproducible manufacturing of patient-specific treatments.

Al, digital twins, and data analytics offer real-time process control and predictive maintenance, while sustainable process design improves yields and efficiency. These advances promise faster, higher-quality, and more cost-effective healthcare solutions.

Despite these advances, challenges remain. What role can synthetic & engineering biology play in expanding the possibilities of bioprocess technologies specifically in the healthcare space? What are the challenges around reproducibility and how can we implement universal standards?

Reflections:

- Complexity of contemporary molecules is enormous and evolving much faster than the bioprocessing design, with current challenges including development and manufacturing of Antibody-Drug Conjugates (ADCs) and translating assembly of final products into cell lines.
- Complex antibody therapeutics hold great promise but face significant barriers in reaching patients due to high production costs, manufacturing complexity, and potential off-target effects.
- Bioprocessing challenges are increasingly solvable, and novel approaches in machine learning and data-driven optimisation offer the potential to unlock significant value from underutilised datasets. Companies and CDMOs hold vast, untapped data resources that could improve manufacturability predictions and process efficiency if anonymised and shared responsibly.
- There is a strong opportunity for the UK and Switzerland to collaborate on innovative clinical trials and improving access to larger markets. Such collaboration could help address current barriers – namely low UK reimbursement levels and Switzerland's small population – which currently discourage companies from launching new drugs in either country.

Case study: A joint <u>SNSF/NIHR funding call</u> supports randomised controlled clinical trials focusing on areas of unmet clinical need. Applications are for joint Swiss-UK projects with lead researchers from both countries, funded through a shared budget of approximately £8 million / 8.8 million CHF. High-quality, collaborative clinical studies that require a cross-border recruitment effort, such as for rare diseases or precision medicine, are supported through the funding call, with lead researchers from both countries.

- Global supply chains for medicines remain fragmented, with limited coordination between nations and siloed pandemic preparedness efforts. Leveraging technological innovation and distributed manufacturing offers a major opportunity to build a more flexible and secure global system.
- There is a lack of funding across the biopharma innovation pipeline from early TRL (technology readiness level) Proof of Concept through to Series A investment. This is stalling momentum across the field.
- UK funding for life sciences manufacturing (e.g., £520M <u>Life Sciences Innovative</u> <u>Manufacturing Fund</u>) primarily targets large pharmaceutical companies with eligibility criteria often excluding startups and SMEs.
- Low appetite for high-risk investment in the UK drives companies to partner with overseas CDMOs in India and China, who often offer flexible pricing, procurement strategies, and risk-sharing models.

Recommendations:

Government:

Expand domestic manufacturing infrastructure and improve funding access for smaller companies to strengthen Switzerland's and the UK's competitiveness.

Encourage and support greater cooperation on innovative clinical trials across the UK and Switzerland.

Improve funding landscape for early stage biopharma commercialisation including for SMEs.

Encourage and support innovative approaches to global cooperation and partnership in medicines manufacturing.

Industry:

Leveraging technological innovation and distributed manufacturing offers a major opportunity to build a more flexible and secure global system.

Unlock new bioprocess innovations and efficiencies by employing machine learning to explore currently underutilised industrial data sets.

The entire innovation ecosystem:

Develop flexible, portable manufacturing facilities using single-use technologies to make production of antibody therapeutics and ATMPs more adaptable and responsive to market and regulatory changes. This represents a major opportunity for Europe to lead in delivering next-generation innovative therapies.

Assess cross-border vulnerabilities and strengthen collaboration to improve supply chain resilience from development through to delivery.

Discussion topic 4: The role of AI in synthetic & engineering biology for health and life sciences

The role of Al in synthetic & engineering biology for health and life sciences is rapidly expanding, transforming how we design, develop, and deploy biological systems for diagnostics, therapeutics, and personalised medicine. What are the primary challenges hindering the integration of Al technology into bioscience research? What are the risks associated with the new technological possibilities that come with Al-driven solutions in synthetic & engineering biology? How can we collaborate across sectors to address all of these challenges?

Reflections:

- Al in biology requires a global standardisation framework to be effective and comparable across borders, by drawing on existing legal frameworks and expanding them to address existing gaps.
- The <u>Swiss National Computing Centre (CSCS)</u> is Switzerland's centralised Al Infrastructure. In contrast the UK has a distributed Al infrastructure model, built around the <u>Alan Turing Institute</u> as a national hub, connected to distributed Al ecosystems and a growing national compute infrastructure, including the <u>Al Research Resource (AIRR)</u> with Isambard-Al (Bristol) and Dawn (Cambridge).
- Biological variability poses significant challenges to the development of standardised, high-quality datasets required for effective AI training, as inherent differences such as sample conditions and measurement techniques introduce substantial inconsistency and complexity that are difficult to uniformly regulate.
- Al models often face limitations from incomplete datasets, especially in DNA synthesis and synthetic & engineering biology. Their reliance on natural rather than engineered cell data, and the underrepresentation of human data, for example, raises concerns about bias and model validity.
- Automation and robotics will be key to scaling synthetic & engineering biology technologies in health and life sciences, and will require a workforce capable of bridging computational and biological expertise.
- Al in combination with synthetic & engineering biology technologies has a high potential
 for dual use, raising ethical and security concerns. There is a lack of clarity on definitions
 and responsibilities for dual-use oversight.

Case study: The <u>Al Security Institute</u> is dedicated to the UK Governments goal of ensuring advanced Al is safe, secure and beneficial. It is conducting research and building infrastructure to understand the capabilities and impacts of advanced Al and to develop and test risk mitigations. The institute is working with the wider research community, Al developers and other governments to affect how Al is developed and to shape global policymaking on this issue.

• International collaboration is key to establish cooperation on standards for responsible Al and data governance.

Recommendations:

Government:

Develop frameworks for cooperation on dual-use oversight, to clarify definitions and responsibilities.

Drive international collaboration to develop frameworks for best practices and shared responsibility for Al and data management.

Industry:

Increase training and clear guidance to raise biosecurity awareness, especially for those working on dual-use technologies.

Educators:

Strengthen education to include more practical applications of AI and improve AI literacy among educators.

The entire innovation ecosystem:

Drive efforts towards routinely collecting metadata (e.g., sample origin, experimental conditions, technical details) to enable standardisation of experimental data.

Case study: The <u>Biolmage Archive</u>, hosted by EMBL's European Bioinformatics Institute, is a a large-scale, centralised data resource to host reference imaging data, making it easier for researchers around the world to store, share, access and analyse biological images. It is a free, publicly available online resource for storing and distributing biological images.

Comprehensive misuse-risk assessments should be a standard part of proposal reviews across all funding bodies, with applicants supported by clear ethical guidance, such as that offered by the <u>Swiss Association of Research Ethics Committees</u>. It is, however, equally important to ensure regulations do not become excessive, since overly stringent frameworks may stifle innovation.

Foster a culture of shared responsibility among Al developers, researchers, and users, promoting critical thinking and preventing overreliance on Al that could lead to scientific complacency and reduced experimental validation.

Discussion topic 5: Barriers to commercialisation

Turning discovery research into commercial success requires the right incentives, but also a supportive innovation ecosystem, particularly for emerging fields like synthetic & engineering biology. How can we shorten the distance between discovery and prosperity, ensuring that problems can rapidly find solutions, and solutions can rapidly access markets? How do we have to work together across government, research organisations, businesses, investors and regulators to make it happen?

Reflections:

- Public support for science investment remains limited compared to health spending, constrained by negative perceptions and low risk appetite.
- Innovation funding would benefit from a higher risk appetite across the UK, while the NHS could drive adoption and development, as demonstrated by mechanisms like the <u>Innovative Licensing and Access Pathway (ILAP)</u>. Preventive health initiatives remain underfunded due to fragmented budgeting.

- Narrow or unprotectable patents and unclear regulatory frameworks continue to discourage investment in synthetic & engineering biology. While the UK has made progress through measures like the <u>Precision Breeding Act</u>, significant gaps remain, particularly in areas such as genetic modification and animal welfare.
- Therapeutics benefit from established pathways to commercialisation, but success metrics remain unclear whether measured by jobs, exits, or long-term impact.
- University success continues to be evaluated primarily by publications and grant income rather than commercial impact.
- Despite strong research and spinout activity, the UK's limited scale-up capacity continues to drive talent and value overseas.
- Both the UK's and Switzerland's small domestic markets and limited public procurement constrain early adoption of new technologies, highlighting the need for policy models similar to US government purchasing schemes. Strengthening operational capabilities in data infrastructure, distribution, and automation will be essential to support broader market uptake.

Recommendations:

Government:

Continue a clear national narrative that frames science as an investment rather than a cost.

Invest in scale-up infrastructure – create national-scale facilities for manufacturing and applied R&D, through mechanisms such as the UKRI Local Innovation Partnerships Fund.

Educators:

Provide incentive structures for academics, acknowledging innovation and impact alongside publications and teaching.

Case study: <u>University Enterprise Fellowships</u> offer academic staff and researchers at the University of Bristol the chance to explore how their work might create impact, whether through commercialisation, social enterprise, or collaboration with industry. Fellows are given protected time and tailored support to explore enterprise opportunities in a way that suits their goals and context.

The entire innovation ecosystem:

Strengthen international collaborations to expand market access, through initiatives like $\underline{\text{UK's Global Expert Missions}}$ and the $\underline{\text{UCL EPFL Startup Exchange Programme}}$.

Concluding remarks

This series of discussions explored how the UK and Switzerland can strengthen collaboration in synthetic & engineering biology for health and life sciences, addressing pressing challenges including regulatory harmonisation, workforce development, bioprocess innovation, responsible Al integration, and improved pathways for commercialisation.

Across all topics, a common theme emerged: the UK and Switzerland share complementary strengths in regulation, research excellence, and innovation. Bilateral cooperation and ecosystem alignment are critical to accelerating innovation and global competitiveness in synthetic & engineering biology for health and life sciences.

The report is intended for a variety of stakeholders with the aim to move forward joint Swiss and UK challenges in the field of synthetic & engineering biology, to amplify the nations' global leadership in health and life sciences innovation.

Annex 1: Summit delegates

Name	Affiliation	Country
Charles Allard	Lonza	СН
Tom Archer	Lucideon	UK
Kasia Averall	Quell Therapeutics	UK
Steve Bagshaw	High Value Manufacturing Catapult	UK
Bettina Balmer	Swiss Parliament (Nationalrat)	СН
Linda Bedenik	BioIndustry Association (BIA)	UK
Christiane Berger-Schaffitzel	University of Bristol	UK
Stan Blein	AstraZeneca	UK
Jeffrey Bode	ETH Zurich	СН
Maddie Cass	BioIndustry Association (BIA)	UK
Samanta Cimitan	Celonic Group	СН
Mark Cresswell	Lucideon	UK
Livjia Deban	Prokarium	UK
Robert Deller	Medical Research Council (MRC)	UK
Julia Djonova	Swissmedic	СН
Neil Goldsmith	BaseLaunch	CH
Joseph Healey	NanoSyrinx	UK
Kerstin Kinkelin	University of Bristol	UK
Tessa Kofmel	Swiss Business Hub UK	UK
Rosie Lindup	BioIndustry Association (BIA)	UK
Rowan McKibbin	UK Research and Innovation (UKRI), Biotechnology and Biological Sciences Research Council (BBSRC)	UK
Angela Osborne	eXmoor Pharma Concepts	UK
Chaewon Park	University of Oxford	UK
Sylke Poehling	Roche, ETH Zurich	СН
Guy Poppy	University of Bristol	UK
Anna Perdrix Rosell	Sixfold Bio	UK
Philipp Schneider	UK Science & Technology Network, British Embassy Berne	СН
Kathleen Sedgley	University of Bristol	UK
Antonia Walpole	Regulatory Innovation Office (RIO)	UK
Oliver Sims	Octopus Ventures	UK
Jeremy Tavaré	University of Bristol	UK
Yiea Wey Te	Zurich Parliament (Kantonsrat)	СН
Anike Te	Lucideon	СН
Natalie Thomas	Swiss Business Hub UK	UK
Vineeta Tripathi	Vitarka	UK
Isabel Webb	Department for Science, Innovation and Technology (DSIT)	UK
Lord Willetts	Regulatory Innovation Office (RIO)	UK
Simon Youlton	Novartis	CH











