Synthetic Biology Leadership Council – Meeting 16
Wednesday 29 March 2017
BEIS Conference Centre, 1 Victoria Street, London SW1H 0ET

Attendees:
Lionel Clarke, Synthetic Biology Leadership Council co-chair
Lord David Prior, House of Lords and Synthetic Biology Leadership Council co-chair

Yvonne Armitage, Knowledge Transfer Network
Louise Ball, Defra
Tim Dafforn, Department for Business, Energy & Industrial Strategy and University of Birmingham
Tim Fell, Synthace and BIA Synthetic Biology Advisory Committee chair
Jackie Hinton, Department for Business, Energy & Industrial Strategy
Alastair Kent, Genetic Alliance UK
Richard Kitney, Imperial College London
Joyce Tait, Innogen Institute, University of Edinburgh (via phone)
Amy Tayler, Synthetic Biology Special Interest Group at the Knowledge Transfer Network

Invited participants:
Steve Chambers, Imperial College London
Jim Haseloff, University of Cambridge
Paul Henderson, Department for Business, Energy & Industrial Strategy
Nigel Scrutton, University of Manchester
Anil Wipat, Newcastle University

Apologies:
Janet Bainbridge, Department for International Trade
Chris Jones, Innovate UK
Ceri Lyn-Adams, BBSRC
Dale Sanders, John Innes Centre
Neil Stansfield, Dstl
David Tew, GSK

1 Welcome & Introduction
Lionel Clarke welcomed everyone to the meeting, noting that (i) Paul Henderson was attending for the first time, (ii) Lord Prior would join the meeting for agenda item 3, (iii) Joyce Tait would participate via phone for agenda items 3 and 5, and (iv) Steve Chambers, Jim Haseloff, Nigel Scrutton and Anil Wipat would join the meeting for lunch and agenda item 4. The apologies were noted.

2 Chair's introduction and group discussion

Steve Bagshaw (co-chair of the Industrial Biotechnology Leadership Forum, IBLF), Judith Batchelar (co-chair of the Agri-Food Technology Leadership Council) and Lionel recently attended a meeting with Greg Clark (Secretary of State for Business, Energy & Industrial Strategy) to inform how they might develop a sector deal for the bioeconomy. To take this forward these three chairs are now working with those of the Chemistry Growth Partnership (CGP) and Medicines Manufacturing Industry Partnership (MMIP) with additional support from BEIS, BBSRC, KTN and others. Lionel noted that in the last five years' language has moved on from 'eight great technologies' to 'industrial strategy' and 'sector deals'. To shape future commitment and maximize impact, synthetic biology now needs to be integrated within one or more sector deals.

Both Lionel and Lord Prior recently participated in an MMIP meeting at AstraZeneca. Lionel described his meeting with Lord Prior immediately before this SBLC meeting. Lord Prior noted that synthetic biology does not feature overtly within the proposed life sciences sector deal, hence he will connect Lionel to Sir John Bell, who leads the life science sector deal. There is the potential for industrial biotechnology and synthetic biology to be combined in an underpinning sector deal that supports three main pillars: life sciences; agri-food technology; and chemicals, materials & energy. Synthetic biology must drive through each of these channels to deliver products that are relevant to an industrial strategy.

The SBLC members reviewed the current status of synthetic biology in the UK, to identify the key issues for with Lord Prior on his arrival for item 3. The main points can be summarised as follows:

- Synthetic biology will help solve real challenges, such as: transforming different feedstocks into fuel as part of a low carbon bioeconomy; intelligent therapeutics; cheaper medicines; better diagnostics; vaccine production; novel drugs; increasing productivity; personalised medicine; cheaper routes to glucose/ engineering organisms to use alternative, more sustainable feedstocks; sustainable food production; etc.
- Synthetic biology can make novel products we can't make any other way. Early opportunities are in high value, low volume products.
- Synthetic biology is an important part of the 4th industrial revolution: a physical, digital and biological convergence. The UK supply chain is working together to form the foundation of the industry. Our strengths are in the design and engineering technology that underpins other industries, for example, there is huge value in designing and producing an organism, which is effectively the software for a hardware bioreactor, which could be based anywhere. Synthetic biology also lends itself to smaller, local, distributed technology rather than large central facilities, which opens up new manufacturing opportunities using cellular factories to re-establish manufacturing across the UK, not just in the South East.
- Synthetic biology has significant innovative and disruptive potential.
- Synthetic biology will generate new industrial entities and skilled, high value jobs across the UK.

- Large companies and Governments often find it difficult to develop and access innovation. They are typically highly analytical and data-driven and can find it difficult to assimilate disruptive technologies.
- Future procurement opportunities could exist with the NHS, especially if it is made more aware of this potential, and willing to help shape the development of these new technologies.
- Standards, tools and characterisation will enable us to truly engineer biology.
- Other issues are also relevant, but not exclusive to synthetic biology.
- The right regulatory framework will enable the industry and attract people and companies to the UK from around the world. Regulations must be agile as they will need to evolve.
- Public funding is still really important. For example, iPhones comprise components that came out of publically-funded projects that were integrated by industry. The DARPA model of funding, with a programme manager and budget for a specific sector, was commended.
- IP in universities needs to be more accessible. University TTOs and companies need to work together for the benefit of the UK economy as a whole.
- What might success look like ten years from now? We should aim to generate ten UK engineering biology companies like ARM, making the UK the world centre for biological software and associated hardware design.

3 Where synthetic biology fits in a sector deal for the bioeconomy

Lionel welcomed Lord Prior to the meeting and the SBLC members briefly introduced themselves, including Joyce Tait who joined the meeting via phone. Lionel noted the apologies.

Lionel explained that the SBLC, which was formed in 2012, published a new strategy in 2016 under the guidance of George Freeman as co-chair. The strategy acknowledges that the science is advancing extremely rapidly and in order to grasp the opportunities that synthetic biology provides we must anticipate the regulatory issues that will inevitably arise. We are now looking at channels to markets to consider what the future of the UK looks like with the benefits of synthetic biology.

Lionel summarised the key points identified earlier, and described a vision similar to that we have already seen for IT in the UK, using an example of ARM technology. The UK is well placed to quickly deliver an integrated 4th industrial revolution.

Lord Prior noted that synthetic biology needs to connect with the ongoing work in the life sciences, and that it is the underpinning science that gives life sciences a competitive advantage. The scale of life sciences makes it an attractive market for synthetic biology. Lord Prior also noted the difficulty in picking industries that don't yet exist in addition to the usual suspects, and what synthetic biology might mean to the layperson.

Lord Prior described four important aspects, two horizontal and two vertical, from the industrial strategy:

- Skills (horizontal): the UK is off the pace with regard to vocational and technical skills. There are plans to pick up the recommendations from the Sainsbury Report on technical skills.
- Academic & applied research (horizontal): there are plans to commit £2bn a year from 2020, and the formation of UKRI will bring Innovate UK closer to the research.
- Place (vertical): too much activity is based in London and the South East. Other areas are left behind with productivity levels lower than London and the rest of Europe.
- Industry sectors (vertical): The UK has world-class manufacturing, batteries, and robotics. We are also world-class in life sciences, but behind Silicon Valley and Boston with regard to start-up companies. Life sciences brings academics to the fore.

Lord Prior asked the SBLC on their views on regulation.

The SBLC noted that, in some cases, such as personalised medicines and gene therapy that are effectively methods of molecular surgery, regulation of the process is important. However, in other cases the regulation by product (US approach), not process, may be more appropriate.

Joyce Tait described her study, which brings the BSI standards-based approach and regulatory frameworks together to make governance systems more proportionate and adaptive to the needs of innovative technologies. In general, the US approach of regulating the final product rather than process by which it was produced (as in the EU) is preferred. For synthetic biology developments if we choose to move away from the EU regulatory framework and do something different as new issues arise, the UK has the opportunity to become an international test-bed for more effective governance approaches. In most cases there is an incentive to retain the EU regulatory system post-Brexit in order to continue to have access to EU markets, but the situation is different, at least for some synthetic biology applications, where the EU regulatory system has prevented the development of a viable industry sector and there is no market to lose. Other members of the SBLC commented that the majority of collaboration is between the UK and the US, China and Singapore, with relatively little in the EU. Joyce used the example of gene edited plants, some of which could be better handled by the plant variety registration system rather than the genetic modification regulatory system. The full report will be delivered to BSI at the start of April 2017.

Alastair Kent reported on the House of Commons Select Committee on genomics and gene editing, which he had attended that morning. The committee is specifically considering the human health applications of genome and gene editing. The current UK regulatory framework is appropriate and sufficiently robust to allow for the transparency that the public requires. However, we have a duty to patients to facilitate the rapid development and safe use of this technology. We must make the necessary transition from research to development, and the infrastructure in the NHS must be ready and able to adapt to the changes required in clinical practice. The

burden of chronic illness on the NHS comes from treating but not curing disease. Genome and gene editing technology will potentially move us into an era where we can cure disease. Alastair explained that some rare blood cancers are already being treated with such technology. In Great Ormond Street Hospital, synthetic biology is being used to apply gene therapy to stem cells to treat immune diseases, providing patients with normal life expectancies.

Synthetic biology provides precision, speed and predictability of the design, which is akin to microsurgery. With more precision comes better health gain, fewer adverse effects, more cures, and less treatment. By reducing the need for regular treatment, we have a huge opportunity to not only create wealth and health benefits through global application, but also to address some of the longer-term issues facing the NHS (such as rising demand and constrained resources).

The SBLC noted that synthetic biology enables the programming and engineering of biology to generate useful products for a range of applications and sectors, not limited to the agri-food tech and pharmaceutical examples given above. Synthetic biology means organisms themselves are the software for the corresponding hardware bioreactors. A parallel was drawn with the ARM chip, which powers laptops and phones. We've been building a supply chain and the companies are emerging and working together to grow the industrial base.

The SBLC attributed the UK's globally strong position in synthetic biology to the big investments that were made early on, but noted that there is a risk of losing momentum. We are beginning to translate our excellent science, but we need to do more. There is a need to develop a clear plan for the next steps within the next 18 months, as current funding plans draw to an end. The research must continue whilst we become more efficient at bridging the gap between academia and industrialisation.

Lord Prior asked the SBLC members for their opinions on the apparent weakness of universities to commercialise their research. Richard Kitney explained that SynbiCITE, the national innovation & knowledge centre for synthetic biology, brings together 20 universities and 45 companies (35 SMEs plus 10 multinational companies) to help in the commercialization of synthetic biology research. The SBLC commented that the approach of a given university will likely differ across faculties. For example, engineering faculties are typically more focused on industrialisation than science faculties, although this is changing: the post-war era was all about intellectual advances but not applied research, but the new generations are increasingly driven by impact. However, this is not always rewarded as promotions boards are often populated with older academics. Similarly, research grants are awarded on account of research excellence, not on a track record in generating spin-out companies. The SBLC commented that the Catapult Centres, Scottish Innovation Centres and Catalyst funds all had a clear translational remit, with the Catalyst mechanism of delivering translational funds considered particularly good. It was recognised that there is still a need to share learning about training entrepreneurs to spread it through the ecosystem and to link into regions and relevant industries.

Lord Prior described the Treasury review of patient capital, which suggests there has been a lack of capital. The SBLC implied that some Technology Transfer Offices (TTOs) in universities overvalue their intellectual property (IP), which has relatively little value at an early stage with added value at much later stages of development. It was suggested that it would be beneficial to take exclusivity away from individual universities and instead provide centres of excellence that anyone can talk to. The SBLC also observed that if a given team has a relatively low stake in a new venture on account of the university taking a large stake, the team is immediately less invested in making it work, which can be discouraging to other potential investors. In the US, universities generally rely on philanthropic payback from successful entrepreneurs rather than taking large stakes in early-stage ventures. It was suggested that Research Council grants, which are funded through Government money, could stipulate the terms under which foreground IP is valued and distributed.

Lord Prior asked the SBLC for two briefing documents.

> **Action 16-1: Urgent, Tim Fell to write a brief summary of the issues relating to university ownership and valuing of IP, which can be sent to Lord Prior via Jackie Hinton.**
>
> **Action 16-2: Urgent, Joyce Tait and Alastair Kent to provide a brief summary on (i) a proportionate and adaptive regulatory system for innovative technologies, and (ii) the ability of the NHS to adopt emerging technologies, which can be sent to Lord Prior via Jackie Hinton.**

Lord Prior noted that he will attend SynBioBeta London 2017 next week and expressed an interest in visiting SynbiCITE.

> **Action 16-3: Richard Kitney to issue a formal invitation for Lord Prior to visit SynbiCITE.**

In relation to their earlier discussion on the relevance of synthetic biology to the life sciences, Lionel asked Lord Prior for an introduction to Sir John Bell.

> **Action 16-4: Lord Prior to connect Lionel Clarke to Sir John Bell.**

4 Science & Technology sub-group

Lionel welcomed Steve Chambers, Jim Haseloff, Nigel Scrutton, and Anil Wipat to the meeting.

Richard Kitney introduced the Science & Technology sub-group, which has representatives from the UKs major synthetic biology research centres. The main aim of the sub-group is to monitor, enhance and integrate work and facilities across the UK, and to aid the use of SynbiCITE for translation support. SynbiCITE's mission is the translation and commercialisation of synthetic biology research, to provide

business and commercial support, deliver training in relevant skills, and to produce an open and positive dialogue with the public. SynbiCITE is well connected to the other centres.

The Science & Technology sub-group mainly focuses on recommendation 2 (maximizing the capability of the innovation pipeline) from the UK strategic plan for synthetic biology 2016. Highlights include the work of the seven major centres and recent investments at Newcastle University, the dry and wet labs associated with the Flowers Consortium, the development of technical standards, and international connectivity to the US, Singapore, and EU universities.

Progress was also reported against recommendation 3 (building an expert workforce) from the strategic plan. Examples include iGEM, student training (undergraduate and postgraduate), and business courses (SynBio LEAP, 4-day MBA and Lean Launchpad).

All the aforementioned participants need to create an activity cluster with all the required elements. The foundries are already collectively addressing liquid handling, and they are moving on to address complexity to better support industrialisation. The synthetic biology ecosystem was compared to the car industry, with end products (cars) designed from many parts from a large supply chain from many different locations.

Richard commented that the green paper on the industrial strategy indicates there will be lots of opportunities for synthetic biology to make an impact: clean energy, healthcare & medicine, manufacturing & materials, and bioscience & biotechnology. Synthetic biology will also benefit from advances in robotics & artificial intelligence.

Nigel Scruton gave a brief overview of SynBioChem, based at the University of Manchester, which is focused on the production of fine and specialty chemicals. Nigel recognises that synthetic biology has the potential to transform the landscape in manufacturing across all industrial sectors. The UK is the 7th largest chemicals producer in the world. The share of bio-based processes in all chemical production is likely to increase to 25% in 2025. SynBioChem builds on ongoing activity at the Manchester Institute of Biotechnology (MIB) and those Manchester-based Networks in Industrial Biotechnology & Bioenergy (BBSRC NIBBs). SynBioChem is focused on high impact fundamental work, much of which is in partnership with industry, plus they are generating licensing agreements, patents and spinouts. Their partnerships are both national and international. With regard to training, SynBioChem: provides online materials and a Massive Open Online Course (MOOC); hosts internal & external workshops; fields successful iGEM teams; offers postgraduate training to those from different disciplines; and facilitates exchange visits. National connectivity is key, and SynBioChem has strong interactions with the other SBRCs, the foundries and SynbiCITE.

Jim Haseloff described the OpenPlant SBRC, which brings together the different perspectives of University of Cambridge and the John Innes Centre, both of which

are ranked very highly in their respective fields. Due to consolidation of ownership among plant biotechnology businesses, three companies will shortly own 80% of the seed business. Open technology, resources and standards help bridge the gap between public research and applications. By putting these in the public domain, other things can be valued and capitalised. Examples of open resources include: the common DNA syntax; the Open MTA, which provides the legal framework for exchanging materials; and the loop assembly technique. OpenPlant's IP tier is based on particular problems or challenges, such as: engineering photosynthesis; carbohydrate engineering; engineering nitrogen fixation; and virus-based systems for bioproduction. Leaf Systems has been established to operate in a contained manner to meet the current regulations on genetically modified organisms, although cell-free systems are also an option.

Other highlights from OpenPlant include workshops in Africa (funded by the Global Challenges Research Fund) to utilise the tools coming out of OpenPlant, outreach activities and the OpenPlant Fund.

Anil Wipat introduced technical standards using the car analogy again. Standards allow us to automate different steps, in this case in the Design-Build-Text cycle, using seamless integration. Industrialisation relies upon reliable, reproducible systems. The Synthetic Biology Open Language (SBOL) is an open language developed by the community to serve engineering biology. Anil is the chair, at present, and another 120 members contribute. SBOL provides both a visual standard and an electronic data standard enabled by appropriate software. The Flowers Consortium uses SBOL and DICOM-SB for coordinated, distributed manufacturing. Richard Kitney explained that DICOM-SB is used for accurately characterising bioparts whilst including information on equipment, protocols and modality data. It is especially relevant to the foundries, which use liquid handling to facilitate assembly and characterisation. The use of a standard makes it much easier to spot anomalies and errors to increase reliability and reproducibility.

Steve Chambers remarked that synthetic biology companies don't always want to call themselves synthetic biology companies, but a large number of companies have been identified that work in the field. Steve noted that waves of innovation are driven by start-ups. 'Biotech 1.0' did not feature many UK companies, but 'Biotech 2.0', the bioeconomy and synthetic biology generate opportunities for the UK. However, not all start-ups are the same, and broadly speaking there are two categories: (i) tech-transfer start-ups (spinouts) in which a technology is licensed from the university, typically funded by the TTO; and (ii) non-tech-transfer startups in which no technology is licensed, typically funded by angels, Venture Capital and Innovate UK. A report will be made on the SynbiCITE website shortly.

In the period 2000-2016, Steve has identified 146 start-ups, of which 79 involved tech-transfer and 67 were considered non-tech-transfer. 111 of these are still active. Together they have raised £660m in private funding, with the tech-transfer companies raising significantly more than the non-tech-transfer companies, although two non-tech-transfer companies are listed on the stock exchange. Private

investment has mainly come from the UK and US. The SBLC noted that only a couple of companies have taken a large amount of private funding, most companies have taken relatively little.

The number of non-tech-transfer start-ups has risen dramatically in the last two years, indicating that more people want to be entrepreneurs. Many, but not all, are in London, and most are linked to well-known academic groups. Steve noted that Innovate UK funding is only a drop in the ocean, lots of private money is needed too. However, more Innovate UK translational funding is still critical to help get early-stage ideas off the ground. The SBLC noted that Innovate UK funding gives companies credibility on account of it being competitive, which is invaluable.

The SBLC and invited participants discussed the difficulty in scaling-up from the laboratory to a larger facility. They agreed that finding the money for SMEs to access the necessary facilities (such as CPI) is hard.

The SBLC asked whether IP is core to the tech-transfer spinouts. Steve explained that this is difficult to measure, and that it is in the best interests of the company to start generating their own IP ASAP.

> **Action 16-5: Richard Kitney and the Science & Technology sub-group to collate data on whether IP is core to spin-outs.**

The SBLC recognises the importance of this data set. Steve agreed and intends to use it to inform SynbiCITE's programmes. Wealth creation and jobs will be the metrics of success.

Lionel thanked the invited participants for their valuable contribution.

5 Governance sub-group

Joyce Tait (via phone) explained that the Governance sub-group has not met since the last open meeting of the SBLC, hence there are no new meetings on which to report. The SBLC approved the minutes of the last meeting, subject to the correction of a couple of typos.

> **Action 16-6: SBLC secretariat to upload Governance sub-group minutes to the website.**

Joyce reflected on Lord Prior's enthusiasm for agile regulation of innovative technologies, such as synthetic biology. The SBLC noted that regulation had been included in previous white papers but that it's been excluded from the recent green paper on the industrial strategy, to which comments are welcome by 17 April 2017. The SBLC agreed that the items in the strategic plan 2016 are still relevant and that it would form a suitable response to the green paper. The discussions with Lord Prior about universities valuing IP and regulations are equally relevant, too.

Action 16-7: Lionel Clarke to submit the UK Synthetic Biology Strategic Plan 2016 as the SBLC response to the Industrial Strategy Green Paper consultation (deadline 17 April 2017).

Richard suggested that SynbiCITE and the other major research centres should submit either a joint or coordinated responses, too.

Action: 16-8: Richard Kitney to liaise with the Science & Technology sub-group to coordinate responses to the Industrial Strategy Green Paper consultation (deadline 17 April 2017).

The strategic plan 2016 is, in effect, our proposal for a sector deal in synthetic biology. The language has evolved from that of 'eight great technologies' to 'industrial strategies' and 'sector deals'. We must stimulate the recognition of the role synthetic biology will play in delivering against important grand challenges.

6 Internal Business

The SBLC briefly discussed the potential relocation of the iGEM Foundation from the US to the UK. In February 2017, KTN facilitated two meetings between iGEM Foundation staff and (i) the UK synthetic biology research centres and (ii) potential funders and other stakeholders. The SBLC agreed that having iGEM in the UK would bring lots of opportunity, but that funding and suitable location issues will need to be addressed separately.

Action 16-9: Lionel Clarke, Richard Kitney and Amy Tayler to seek an update from the iGEM Foundation during SynBioBeta London 2017.

The SBLC approved the minutes of the last meeting and Lionel noted the actions as done.

Action 16-10: SBLC secretariat to upload the approved minutes of SBLC15 to the website.

Amy Tayler briefly introduced her paper regarding SBLC membership, but noted that the SBLC was not quorate to be able to act upon it. The SBLC agreed that it should be an agenda item at the next meeting, at which time we could also ask whether any current members of the SBLC wish to leave. It would be sensible to align the membership with the sector deals and industrial strategy, as and when more details emerge, and to consider how best to interact with UKRI.

Action 16-11: SBLC secretariat to include (i) SBLC membership and (ii) SBLC interactions with UKRI on the agenda for SBLC 17.

Amy Tayler suggested that a brief update on the progress made since the publication of the strategic plan 2016 will be circulated for consideration by the SBLC shortly.

7 AOB

Lionel introduced the topic of biosecurity threats. Multiple workshops appear to have converged on the same small set of conclusions. The community must feel empowered to respond if they see a concern, but we still need a clear UK reporting line. At present, if someone was concerned with an enquiry they would initially raise it with their supervisor, but it's not clear to whom it could be escalated. It needs to be a point of contact that understands the context in which that call is made. Lionel will shortly discuss this with the Home Office with regard to the cross-Government biosecurity strategy.

The SBLC asked for the slides from the invited participants be made available for circulation.

> **Action 16-12: SBLC secretariat and Richard Kitney to get approval to circulate the slides from this meeting.**

Lionel thanked the SBLC members for their participation before closing the meeting.

Summary of actions arising from SBLC15

Action 15-1: SBLC secretariat to consolidate and share the expanded list of potential new members in the new year.

Action 15-2: SBLC secretariat to share the revised template for the register of interest for completion by the SBLC.

Action 15-3: SBLC secretariat to circulate a Doodle Poll to arrange dates for meetings in 2017.

Action 15-4: Amy Tayler to coordinate a summary of activities against the recommendations in the strategic plan ahead of the next meeting.

Action 15-5: SBLC secretariat to draft the minutes of this meeting.

Summary of actions arising from SBLC16

Action 16-1: Urgent, Tim Fell to write a brief summary of the issues relating to university ownership and valuing of IP, which can be sent to Lord Prior via Jackie Hinton.

Action 16-2: Urgent, Joyce Tait and Alastair Kent to provide a brief summary on (i) a proportionate and adaptive regulatory system for innovative technologies, and (ii) the ability of the NHS to adopt emerging technologies, which can be sent to Lord Prior via Jackie Hinton.

Action 16-3: Richard Kitney to issue a formal invitation for Lord Prior to visit SynbiCITE.

Action 16-4: Lord Prior to connect Lionel Clarke to Sir John Bell.

Action 16-5: Richard Kitney and the Science & Technology sub-group to collate data on whether IP is core to spin-outs.

Action 16-6: SBLC secretariat to upload Governance sub-group minutes to the website.

Action 16-7: Lionel Clarke to submit the UK Synthetic Biology Strategic Plan 2016 as the SBLC response to the Industrial Strategy Green Paper (deadline 17 April 2017).

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