



**Synthetic Biology Leadership Council
Meeting 14
Thursday 14th July 2016**

BIS Conference Centre
1 Victoria Street, London SW1H 0ET

Attendees

Prof Lionel Clarke	Co-chair, SBLC
Prof Janet Bainbridge	UKTI
Dr Martin Cannell	Defra
Prof Tim Dafforn	Department for Business, Innovation & Skills and University of Birmingham
Sue Dunkerton	Knowledge Transfer Network
Mike Edbury	Government Office for Science
Dr Tim Fell	BioIndustry Association and Synthace
Dr Jackie Hinton	Department for Business, Innovation & Skills
Dr Chris Jones	Innovate UK
Alastair Kent	Genetic Alliance UK
Prof Richard Kitney	Imperial College London
Dr Rowan McKibbin	RCUK
Prof Neil Stansfield	Dstl
Prof Joyce Tait	Innogen Institute, University of Edinburgh
Dr Amy Tayler	Synthetic Biology Special Interest Group, Knowledge Transfer Network
Dr David Tew	GSK

Invited Guests

Stephen Axford	Department for Business, Innovation & Skills
Henry Womersley-Smith	Office for Security and Counter-Terrorism, Home Office

Apologies

George Freeman MP	Department for Business, Innovation & Skills and Department of Health, Co-Chair, SBLC
Dr Helen Bodmer	Department for Business, Innovation & Skills
Prof Dale Sanders	John Innes Centre

1 Welcome & Introduction

Prof Lionel Clarke welcomed everyone to the meeting, particularly Prof Neil Stansfield (Dstl) who attended for the first time as a standing member of the SBLC, and Henry Womersley-Smith (Home Office) who attended specifically for item 7 (UK

biosecurity strategy). Lionel explained that Alastair Kent (Genetic Alliance), Michael Edbury (Government Office for Science) and Stephen Axford (Department for Business, Innovation & Skills) would join the meeting later. The SBLC members introduced themselves.

Lionel reminded the SBLC that *Biodesign for the Bioeconomy, UK Synthetic Biology Strategic Plan 2016* contains a series of recommendations, against which we must track progress and record our activities.

Following Theresa May's appointment as Prime Minister the day before this meeting, ministerial appointments were being made during the course of the meeting. The SBLC noted George Freeman's enthusiasm for synthetic biology, and considered the best timing for future ministerial briefings (e.g.: ahead of the Autumn Statement of 2017 budget), not just for a new minister in BIS but also in UKTI. It is sensible to position synthetic biology alongside the upcoming innovation plan.

2 Internal Business

The actions arising from SBLC 13 can be found in Appendix 1. The following actions have been marked as done: 13-1, 13-2, 13-5, 13-6, 13-7, 13-8, 13-10, 13-12, 13-13, 13-14, 13-16 and 13-17.

Actions 13-3 and 13-4 are ongoing. SBLC members have been asked to update the dynamic spreadsheet tracking activity against the recommendations in *Biodesign for the Bioeconomy, UK Synthetic Biology Strategic Plan 2016*.

Actions 13-9 and 13-11 will be updated under item 4 (Science & Technology sub-group).

Action 13-15 has been completed and will be discussed under item 3 (SBLC Membership and Future Participation).

Action 14-1: SBLC secretariat to make two amendments to the minutes of SBLC13 and upload to the SBLC website.

3 SBLC Membership and Future Participation

The SBLC membership is small to facilitate dynamism, but the wider sub-groups and invited speakers allow other groups to engage with the SBLC directly. For example, Lionel has spoken to the individual RRI representatives from the SBRCs, and the SBLC was supportive of bringing them collectively to a future SBLC meeting. The Science & Technology sub-group intends to give a formal presentation to the SBLC in March 2017. Additional attendees will be invited as and when the agenda requires it.

The SBLC considered that the current membership lacks expertise in commercialisation & investment and lacked sufficient representation from different industrial sectors. The SBLC membership needs to better reflect the emphasis on tools, technologies and end-markets. A stronger industrial presence will be particularly important as the SBLC discusses co-investment opportunities with

Government. To keep numbers relatively low, it may be necessary to move some of the existing SBLC members to a sub-group.

The SBLC acknowledged the work Lionel is doing with the chairs of the other relevant leadership councils under the auspices of the Bioeconomy Programme Board. However, the SBLC also needs to better define its relationship with the other leadership councils operating in particular end markets.

Action 14-2: All SBLC members to send suggestions for potential new (predominantly industrial) members with a paragraph of justification to Amy Tayler by Thursday 28th July 2016.

Dr Amy Tayler (Synthetic Biology Special Interest Group, Knowledge Transfer Network) has drafted a SBLC members' declaration of interest form, based on one used by the BBSRC strategy advisory panels, prior to this meeting. The SBLC considered it too focused on academia and not suitable for the needs of the SBLC. The SBLC noted that the expertise that brings them around the table means there are inevitable conflicts with particular discussions. However, a register of interests is intended to improve the transparency under which the SBLC operates, rather than to exclude members from individual discussion topics.

The SBLC recommended a consistent approach be taken across the five leadership councils operating under the bioeconomy program. The SBLC agreed that members should declare where their grants have come from, but not what they are. Changes could be made at each meeting.

Action 14-3: SBLC secretariat to revise declaration of interest template and circulate for comment and completion.

Action 14-4: Once the ministerial co-chair has been confirmed, SBLC secretariat to poll the SBLC for 2017 dates.

4 Science & Technology sub-group

Prof Richard Kitney (Imperial College London) described the recent activities of the Science & Technology (S&T) sub-group. Richard is working with Prof Dale Sanders (John Innes Centre) to produce some formal terms of reference for the S&T sub-group. The group has good representation from across the research centres, primarily at the director level. Lionel has agreed to participate, too. The S&T sub-group intends to give a formal presentation to the SBLC at the meeting in March 2017. The key objective is to integrate the research community and represent everyone through a common voice. Sub-group meetings have been scheduled to take place shortly before SBLC meetings to facilitate contributions. The S&T sub-group is keeping a record of metrics and activities against recommendations 2 & 3 of *Biodesign for the Bioeconomy, UK Synthetic Biology Strategic Plan 2016*.

Action: 14-5: Amy Tayler and Richard Kitney to record Science and Technology sub-group activities against the recommendations in the strategic plan.

The most recent meeting of the S&T sub-group focused on maximizing the capability of the innovation pipeline, whereas the one before focused on training & education and produced a document on all courses available in the UK). The participants carried out a SWOT analysis (strengths, weaknesses, opportunities & threats) on synthetic biology research. The SBLC recognised that the field is moving very quickly, the technology landscape is constantly changing, and that some technologies can be commercialized more quickly. There is clearly still a need to support world-class, underpinning science. However, the SBLC considered that items identified through the SWOT analysis focused on technology-push rather than technology-pull from industry, and that the group would benefit from aligning the analysis with the needs of industry, whilst considering the capacity of business for adopt synthetic biology approaches. This would better serve the broader aspirations of *Biodesign for the Bioeconomy, UK Synthetic Biology Strategic Plan 2016*, too. The S&T sub-group could consider recruiting some industrial members to match the technology-push with the industry-pull, which would make the activities of the relevant research groups more industrially relevant. Cambridge Consultants is currently looking at all the start-ups that are on the SynBioBeta list to help map out that space.

The SBLC considered how to better bridge the gap between the R&D funded by the research councils & Innovate UK and that supported by private investment. Dstl, for example, already funds projects across a wide range of technology readiness levels (TRLs). Dstl's independence and impartiality brings together researchers, SMEs and large companies around projects with applications in defense and other commercial sectors to drive success for the supply chain. Dstl doesn't retain the IP, which give start-ups more freedom.

The Government is already exploring opportunities for procurement to drive innovation. Prof Tim Dafforn (Department for Business, Innovation & Skills and University of Birmingham) explained that the challenge Business Program has engaged with lots of innovative technology sectors, and procurement is raised in every one. Companies benefit from logging transactions as revenue rather than grants as it helps them leverage private investment.

The SBLC did not consider it appropriate to only align SBLC activities to particular funding competitions, such as the biomedical catalyst, given the current uncertainty around funding and Innovate UK's move toward fewer, broader competitions. The SBLC acknowledged the work of the SynBio SIG in identifying opportunities for synthetic biology in the new Innovate UK delivery plan, and consider advanced therapeutics an area to explore further.

The SBLC considered how the S&T sub-group could facilitate the use of synthetic biology in the developing world, especially given the injection of funding into the Global Challenges Research Fund (GCRF).

Prof Joyce Tait (Innogen Institute, University of Edinburgh) requested that the minutes of Governance sub-group (GSG) be shared with the S&T sub-group

Action 14-6: SBLC secretariat to send minutes of the Governance sub-group to Richard Kitney for circulation amongst the Science and Technology sub-group.

5 Governance Sub-Group

The minutes of the 7th and 8th GSG meetings were agreed.

Action: 14-7: SBLC secretariat to upload the minutes of the 7th and 8th Governance sub-group meetings to the SBLC website.

Joyce first discussed the membership of the GSG and SBLC, explaining that, in some contexts, it might be appropriate to involve EPSRC as well as BBSRC. For example, EPSRC has an initiative with Friends of the Earth, in which they are mapping the stakeholder community. This could inform a dialogue with investors and stakeholders regarding what they would like to see coming out of synthetic biology. However, consideration must be given as to how to deliver such engagement without adding to the SBLC membership.

Joyce introduced a proposal for proportional and adaptive governance, on which a paper had been circulated around the SBLC members prior to the meeting. The regulatory system for genetically modified organisms (GMOs) and synthetic biology is widely seen as not fit for purpose. Pre-EU referendum, there were moves to populate the Generally Regarded As Safe (GRAS) category. However, Brexit gives the UK an opportunity to review its regulatory practices and align them more with the rest of the world to benefit of the UK. We could gain a broader international market with countries that don't currently see us as viable partners. In the long-term, it could have a knock-on effect in changing the EU system. In most other areas it will be valuable to match the EU regulatory system as close as possible to facilitate market access. However, there is huge opportunity in genetic modification, synthetic biology and advanced innovative biotechnologies.

Joyce is working with BSI to convene a high-level working group to develop a strategy for the UK to constructively consider industry and safety, effectiveness, quality etc. The project, which is estimated at £70k for delivery in March 2017, will obtain a broad overview of a suite of industry voices to produce a paper or report for the policy community indicating where the opportunities are, the size of the opportunity, and what we need to do to make sure it is workable.

The SBLC discussed the proposal, suggesting not only that UK regulators be involved (such as Defra, HSE, and MHRA) but also US regulators, who are considering the US regulatory system. Regulations are often interpreted by lawyers, who aren't necessarily as close to the cutting-edge science, so it was recommended that they be involved, too.

Previous discussions with industrial communities found support for using standards to make the regulatory system more adaptive and proportionate. Whilst it is often preferable to regulate a product rather than a process, there are some processes that need regulation, such as gene therapy, and continuous processes that won't have batch numbers. The SBLC noted the distinction from the development of technical standards, which tends to be an international activity involving industry.

The SBLC agreed that this is a significant and unique opportunity for the UK, and that it could be an early and significant good news story for Government. Discussions in Europe about the precautionary principle have involved many of the right people, but it was always in the framework of the EU. Other examples of countries benefitting from different regulatory frameworks were discussed, such as proton beam therapy booming in Switzerland as it has flexibility from the EU regulations. If the UK can establish the right framework, it will attract business to the UK. For example, a UK-equivalent of the FDA advanced therapies regulation would be hugely beneficial. However, it was noted that care must be taken during Brexit negotiations.

The SBLC considered what will likely happen at the end of the project. Joyce explained that it should be useful for Defra, HSE, MHRA and other Government departments dealing with regulation. The report will be framed to lay out the opportunities without being constraining.

Beyond synthetic biology, the SBLC considered whether Government could build a broader regulatory system for opportunity.

The SBLC supported the proposal. Dr Tim Fell (BIA and Synthace) agreed to discuss the proposal with the BIA and Lionel/ Prof Janet Bainbridge (UKTI) with the appropriate ministers, as and when the time comes.

Action: 14-8: Joyce Tait to expand proposal (late paper 4a) to allow wider consultation with the BIA SBAC (via Tim Fell) and with the appropriate Ministers (via Lionel Clarke and Janet Bainbridge).

6 Standards

Dr Chris Jones (Innovate UK) reported on a meeting held in partnership with the SynBio SIG in which the following stakeholders convened to discuss standards for synthetic biology: Croda, Dr Reddy's, Synthace, Imperial College London, University of Cambridge, University of Edinburgh, NPL, LGC, and BSI together with Innovate UK and SynBio SIG.

BSI has compiled a report from an industry consultation. When asked what standards could do for synthetic biology, they in turn asked what synthetic biology could do for them. Large companies (the end-users) need a technology that works. SMEs and academics (the technology providers) can provide it, either through proprietary or open source tools. However, there is still an issue with identifying (or not) with synthetic biology.

It is important for the UK to be represented on the appropriate US National Institute of Standards & Technology (NIST) working groups (they are very open to global participation). Uptake of SBOL & DICOM-SB is limited but growing.

Repositories are well used by academia but not by industry. However, as parts are better characterized they will be more attractive. However, industrial end users need to be confident that they have freedom to operate (FTO).

In conclusion, the UK community was encouraged to get involved in the relevant NIST groups, for funders to consider encouraging their grant holders to adopt standards, for efforts to continue with regard to standards for metrology and reference materials, and for projects on standards to be made more visible.

Tim Fell described the work that Synthace is doing on the Antha, an open source language for biology. The way in which experiments are designed upfront makes the data compatible and comparable (an approach shared not only by Synthace but also the UK foundries).

The SBLC acknowledged that biology is about to become a reproducible science for the first time, but that standards keeps throwing us. There appears to be a mismatch between the standards wanted by academia (definitions, language etc.) and those wanted by industry (protein characterisation etc.), and it is important to consider the industry-pull. Industry will only adopt standards when they see an increase in productivity, and the business case for standards is not yet there. There is also a risk that the early adoption of standards in an emerging technology area will focus too rapidly in one area whilst blocking another, so reducing the variety of products being developed. However, there is also a recognition that standards will evolve and develop over time.

Alistair Kent (Genetic Alliance UK) explained that regulations often demand the repetition of work that has already been done and outcomes that are already known. The bringing together of standards and regulation could reduce the need for repetition and reduce the overall cost of development.

7 UK biosecurity strategy

Dr Jackie Hinton (Department for Business, Innovation & Skills) explained that UK Government has an internal biosecurity strategy that is undergoing review with the intention of producing a public version. The strategy covers national and international threats, both natural and deliberate, and the possible implications on human and animal health. Jackie is involved to link in existing dual-use guidelines and concordats.

Henry Womersley-Smith (Office for Security and Counter-Terrorism, Home Office) explained that the aim is to deny terrorist access to dangerous materials. Key legislation already governs security of the most dangerous pathogens and toxins: laboratories must notify the Home Office if they are using them, and they receive

advice on the security of the laboratory from a local representative. This activity is led by the National Counter Terrorism Security Office (NCTSO). The NCTSO is currently holding a series of workshops to review the legislation and list of pathogens & toxins (schedule 5). However, the current regulation does not cover fragments of DNA, only whole genomes, demonstrating how developments in technology can outpace the legislation.

Project Revise is raising awareness in university laboratories about chemicals that could be used for other purposes. There is an opportunity to add biological substances and research of concern. It is recognized that the UK needs a more cohesive strategy. These issues need to be considered by the research councils and not left until the stage of publication. The SBLC commented that the channel for dissemination is important as academics may not respond well to security agencies telling them what to do. An effective communication route could be through the SBLC and SynBio SIG.

Seven countries have come together to focus on the dual-use of research of concern, the legislation, raising awareness of appropriate codes of conduct. A paper will be presented in November.

The SBLC explained that the International Gene Synthesis Consortium approach being adopted by DNA synthesis companies (and now some of the UK foundries) is to screen what is being requested and by who. Reporting is currently channeled through Ed Yu (special agent of the FBI responsible for synthetic biological weapons), who is an approachable, well-known member of the international synthetic biology community. Ed is training experts around the US to provide more local support. The UK community would welcome a similar arrangement in the UK, but Richard has not had any luck engaging with the Metropolitan Police.

A top-down regulatory approach will struggle in this space. We have a dichotomy: synthetic biology is technical and difficult, but the emerging technology makes it easy for even non-experts. We cannot restrict access to materials. Instead, we have to detect threatening activities, analyse them and respond, which is analogous to our approach to cybersecurity.

The detection of biosecurity threats is likely to be difficult and sophisticated, but the equipment should be cheap, distributed, easy to use and easy to read the result. We don't yet fully understand how synthetic biology will revolutionise the threat space, and we don't yet know what a new threat will look like, so we need a non-signature method of detection. Airports have equipment that can detect chemicals instantly, but it currently takes much longer to detect biological agents. If we can speed up detection of a biological threat, we also need to speed up our response to that threat.

In addition to physical agents, there is a need to protect digital information, too.

Government funding in this areas could strategically coordinate a national program in response to a national threat and a national strategy. Henry suggested we get in contact with Hazel Taylor (National Counter Terrorism Security Office, Home Office) to convene a group that can inform Government of the emerging threats.

The communication strategy around biosecurity must recognise that synthetic biology is a transformational technology with huge potential for good and bad: we need to promote the opportunity for desirable applications, and mitigate the risk of others. It is important that concerns about biosecurity don't inhibit our ability to respond to them. Serious threats are most likely to come from nature or state-sponsored activities, and synthetic biology allows us to create distributed diagnostics, antibiotics, and vaccines rapidly.

Action 14-9: Henry Wormersley-Smith to connect the SBLC to the National Counter Terrorism Security Office.

8 International partnerships

The UK can be considered open for international partnerships with Europe, US, China and beyond. The SBLC discussed opportunities in the developing world, using countries in Africa as a worked example. DFID, OECD, UKTI and the FCO SIN could support interactions with the relevant countries. The UK is working with both the US and Singapore on national security and defense.

BBSRC (but not Innovate UK) is a sponsor of the upcoming ERA-Net CoBioTech (Cofund on Biotechnologies), which will provide a mechanism for EU collaborative projects.

SynBioBeta recently organised a fact-finding trip to China, during which delegates learned about the start of play. China plans to invest \$2-3Bn in synthetic biology and associated technologies. The UK participants (Lionel Clarke- SBLC; Richard Kitney – Imperial College London; Paul Freemont – Imperial College London; and Richard Hammond – Cambridge Consultants) explored potential collaborations. BSI is also working with China on business opportunities to develop standards in the fields of graphene and synthetic biology. Both Richard and Joyce are working with BSI on this matter, which could fit with the project on regulations.

The SBLC noted that there is a tension in international partnerships: we have to be quite clear that a given collaboration that will add value to the UK, and not just because they are good scientists.

Neil has a report on synthetic biology expertise around the world, which he will share with the S&T sub-group.

Action 14-10: Neil Stansfield to share global synthetic biology report with Richard Kitney to circulate to Science and Technology sub-group.

9 Bioeconomy update

Stephen Axford (Department for Business, Innovation & Skills) was invited to provide an update on behalf of the BIS bioeconomy team. The SBLC introduced themselves. Stephen reflected upon the language being used in Government. Teresa May states we need a proper industrial strategy. George Freeman has been using language around the bioeconomy for more than a year, stating it can '*heal, feed and fuel the world*'. As such, a UK bioeconomy strategy is under development by the Bioeconomy Programme Board, which brings together the five relevant leadership councils. There is a lot of goodwill in Whitehall for a bioeconomy strategy (including Defra), but lots of challenges too. The aim is to bring together the emerging and enabling technologies with the markets. The different departments are working on a definition of the bioeconomy. In parallel there will be a communications exercise, bringing it all together to deliver better outputs.

Stephen and the SBLC discussed the current regulatory system, which has forced chemical precedents onto biology and subsequently hindered lots of useful R&D. It would be beneficial to have a series of projects to change regulation X in Y years. For example, populating the GRAS category as a first step.

Stephen and the SBLC considered the 4th industrial revolution (bringing together the digital, physical and biological domains), in which synthetic biology will play a key role. It was recommended that e-infrastructure be included. There are already existing channels to which synthetic biology can contribute, and new channels emerging directly from synthetic biology.

Stephen admitted that Brexit would, no doubt, bring both problems and opportunities.

Lionel shared the working statement on the bioeconomy, to which the SBLC provided feedback.

Action 14-11: All SBLC members to provide amendments to UK bioeconomy statement to Lionel Clarke by cop Monday 18th July 2016.

11 Plans for next meeting (open)

The open meeting of the SBLC will take place on 24th November 2016. Amy introduced a paper, which summarised the formats that have been used previously. It is important that the open meeting benefits both the SBLC members and the delegates.

The SBLC was most supportive of (i) an agenda item on RRI to be delivered collectively by the relevant members of the SBRCs and (ii) a World-Café style breakout session to ask the community what they want the SBLC to do for them, what synthetic biology should do for them, and synthetic biology in a post-Brexit world. The SBLC consider adequate Q&A time to be very important.

Action 14-12: Amy Tayler to draft agenda for SBLC15 open meeting and circulate for comment.

12 Plans for Ministerial briefing

Unfortunately, George Freeman (Department for Business, Innovation & Skills and Department of Health, co-chair, SBLC) was unable to attend the meeting. Lionel invited SBLC members to consider what key points they want to highlight for the minister.

Action 14-13: All SBLC members to send Amy Tayler highlights from SBLC14 for inclusion in a Ministerial briefing by cop Thursday 21 July 2016.

13 AOB

SBLC members were invited to raise any additional points before the meeting was closed.

Joyce raised concern that in the context of RRI, it is not just innovators that have to be responsible: all stakeholders should engage in a responsible manner. In her work with BSI she is exploring a standard for stakeholder engagement, which will include the kinds of evidence that can be brought to a discussion and how decisions are made.

Tim Fell shared the news that Synthace was recently named one of the World Economic Forum's technology pioneers for 2016. It was the only UK company on a list of 30, 5 of which were in the synthetic biology space.

Action 14-14: SBLC secretariat to draft SBLC14 minutes.

Summary of actions arising from SBLC 13

Action 13-1: Amy Tayler to upload all approved SBLC and GSG minutes to the relevant webpages.

Action 13-2: SynBio SIG to update spreadsheet of recommendations from the strategic plan as discussed during the meeting.

Action 13-3: Once settlements from BIS are known and allocated, all (especially RCUK and Innovate UK) to revisit the updated spreadsheet of recommendations from the strategic plan and indicate where they can take a lead or make a contribution.

Action 13-4: Those taking the lead in delivering the recommendations from the strategic plan to produce one sentence describing what they are going to do (see new column in spreadsheet).

Action 13-5: KTN to consult BIA regarding a potential workshop or activity on the role of SynBio in healthcare.

Action 13- 6: KTN to consult the cell and gene therapy catapult about the use of advanced genetic constructs in gene therapy and whether they identify with the SynBio community.

Action 13- 7: Amy Tayler to circulate Lionel Clarke's updated metric sheet.

Action 13-8: Amy Tayler to forward link to AHTEG consultation outcome.

Action 13-9: Anne Osbourn and Richard Kitney to ask the Science and Technology subgroup to give an inventory of (i) working with the 3rd world and (ii) healthcare applications of synthetic biology to make a story for the Minister and (iii) an updated 'Carlson Curve' for DNA synthesis.

Action 13-10: Amy Tayler to forward link to whole genome sequencing and sharing for the benefit of the patient.

Action 13-11: Science & Technology sub-group to link to learned societies regarding education and training.

Action 13-12: Joyce Tait and Richard Kitney to forward dates of the sub-group meetings to Amy so she can make sure SBLC minutes and draft agendas are available in a timely fashion.

Action 13-13: Lionel Clarke to invite Prof Neil Stansfield, Dstl, to join SBLC.

Action 13-14: Joyce Tait to invite Robert Doubleday to join GSG.

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Action 13-15: SynBio SIG to consult BBSRC regarding a register of interest for the SBLC.

Action 13-16: Andy Boyce to invite LGC to the standards meeting on 27th April 2016.

Action 13-17: Amy Tayler to produce SBLC 13 minutes and a 1-page digest for the minister.

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