Synthetic Biology Leadership Council
Minutes of the meeting held on Wednesday 16th October 2013
Council Room, The Royal Society, 6-9 Carlton House Terrace, London SW1Y 5AG

Attendees

Co-chair: Prof Lionel Clarke (Shell Global Solutions).

Leadership Council: Prof Janet Bainbridge (UK Trade and Investment - UKTI); Carol Boyer-Spooner (Chemistry Innovation Knowledge Transfer Network – CI KTN – and Industrial Biotechnology Leadership Forum - IBLF); Dr Belinda Clarke (Technology Strategy Board - TSB); Paul Gemmill (Biotechnology and Biological Sciences Research Council – BBSRC – and Research Councils UK - RCUK); Prof Richard Kitney (Imperial College London); Sharmila Nebhrajani (Association of Medical Research Charities); Prof Joyce Tait (Innogen Centre, University of Edinburgh); Prof Janet Thornton (European Bioinformatics Institute - EBI).

Observers: Shamimara Ahmed (Research Funding Unit, Department of Business, Innovation and Skills - BIS); John Betts (Research Funding Unit, BIS); Mike Edbury (Government Office for Science); Ron Egginton (Research Funding Unit, BIS); Dr Ben Sheridan (British Standards Institution – BSI).

Secretariat: Dr James Brown (Director of the Synthetic Biology Special Interest Group - SynBio SIG – and Biosciences Knowledge Transfer Network - BKTN); Dr Amy Tayler (SynBio SIG, BKTN); Chris Warkup (Director of BKTN).

Apologies: Rt Hon David Willetts (Universities and Science Minister, BIS, Co-chair); Dr Simon Dolan (GlaxoSmithKline, council member); Prof Dale Sanders (John Innes Centre, council member).

Open meeting registered observers: Simon Bayly (Epiphany Capital); Laura Bellingan (Society Of Biology); Aurélie Bovi (The Biorenewables Development Centre); Linda Brooks (Life Technologies); Martin Cannell (Defra); Charis Cook (GARNet); Tim Dafforn (University Of Birmingham); Melanie Duffield (Dstl); Tim Fell (Synthace); James Field (Lab Genius); Paul Goddard (Protein Technologies); Angray Kang (Queen Mary University of London); Preben Krabben (Green Biologics); Catie Lichten (Research Fortnight); Alex Mair; Claire Marris (King's College London); Kate Miller (University of Bristol); Mark Morrison (Institute of Nanotechnology); Claire Mouchot (French Embassy); Simon Napper (Technology Strategy Board); Helena Paul (ExoNexus); Anna Peacock (University of Birmingham); Edward Perello (Desktop Genetics); Nick Rollings (Cambridge Consultants); Megan Rumford (Terrapinn); Nigel Saunders (Brunel University); Ben Scales (Terrapinn); Hilary Sutcliffe (MATTER); Lesley Thompson (EPSRC); David Uffindell (BIS); Sean Ward (Synthace).

1 Welcome and Introductions

The chair welcomed the attendees to the third full but first open meeting of the Synthetic Biology Leadership Council (SBLC). The SBLC is committed to hold one open meeting per year. The vast majority of those that registered an interest in attending this open meeting have been accommodated. However, the SBLC will try to secure a larger venue for future open meetings. The chair explained that meeting was being recorded to capture material for future reference and that by being present in the room, delegates were implying consent to a recording being made for this

purpose. The chair highlighted the full agenda and kindly asked speakers to keep to time and participants to save their questions for the allocated Q&A session.

The chair, council members, observers and secretariat introduced themselves. The chair specifically welcomed Ben Sheridan (British Standards Institution), who was invited to this meeting to participate in agenda item 5 to discuss recent meetings on standards and intellectual property (IP). The chair noted the three apologies from Rt Hon David Willetts (Universities and Science Minister, BIS, Co-chair), Dr Simon Dolan (GlaxoSmithKline) and Prof Dale Sanders (John Innes Centre). The chair acknowledged that, to date, his co-chair, Rt Hon David Willetts, has been 100% committed to every meeting. Joyce Tait (ESRC Innogen Centre, University of Edinburgh) was delayed but joined the meeting shortly after it started.

2 Internal Business: Minutes and actions from the last meeting

The actions from the meeting held on Wednesday 17th July 2013 were reviewed and discussed. These are included in Annex 1 for reference.

Actions 1 and 2.

Noted as done.

Action 3

James Brown explained that two private investment funds have approached the Synthetic Biology Special Interest Group (SynBio SIG). The details of these discussions are understandably confidential. In the margins of the SynBioBeta conference in November 2013, the US branch of the Science and Innovation Network (SIN) will hold a series of company visits and an investor roundtable. As a follow-up to this event, the SynBio SIG is considering running a series of UK-based events in Spring 2014 to bring together potential investors and UK start-up companies and look to improve the synthetic biology UK 'business birth rate'.

Action 4

Noted as done. If anyone has any difficulty accessing the 'SBLC Member Space' folder on Dropbox, please contact Amy Tayler.

Action 5

Janet Bainbridge provided some background on UKTI, which encourages inward investment in the UK. The next UKTI marketing campaign will focus on the eight GREAT technologies underpinning innovation. Synthetic biology is seen as an enabling technology with the potential to underpin a variety of sectors, and has therefore been chosen as one of these eight GREAT technologies. A dialogue between UKTI and the SBLC is key. The campaign has a budget of £2M over three years, and is likely to launch early in 2014.

Action 1: Janet Bainbridge and the UKTI marketing team to consult the SBLC on key messages regarding synthetic biology and the GREAT campaign.

Action 2: The resultant UKTI GREAT marketing materials to be circulated to the SBLC via the secretariat.

Action 6

James Brown explained that a lot of work went into the roadmap workshops, and that lots more could be gained from the outputs. James intends to report back to the SBLC at the next meeting, when we can also take stock of the first year of the leadership council.

> ***Action 3: Revisit the outputs from the roadmap workshops and report back at next SBLC meeting (James Brown)***

Action 7

An update on activities can be found in paper 2 of the meeting papers (and will be reviewed under item 3). The paper captures activities from all five of the research councils involved in the synthetic biology working group. James Brown thanked Paul Gemmill, Belinda Clarke and Ron Egginton for their input. Synthetic biology technologies are still at an early stage. However, it is expected that some case studies will come together in the next 12 months. 'www.SynBioLC.org' has been registered and will soon redirect to the SBLC pages on the SynBio SIG website.

> ***Action 4: SBLC secretariat to upload paper 2 to the SBLC pages of the SynBio SIG website, and to convey the information in a more digestible form.***

Neither the suggested 'branding' of the SBLC nor the 'badging' of UK activities in synthetic biology have been taken forward yet.

> ***Action 5: Explore opportunities to (i) brand the SBLC and (ii) badge UK synthetic biology activities, and report back at next meeting (James Brown, Janet Bainbridge and Ron Egginton).***

Action 8

To be covered under item 4 (paper 3).

Action 9

To be covered in item 6 (paper 4).

Action 10

Paul Gemmill noted that Andy Boyce (BBSRC, andy.boyce@bbsrc.ac.uk) is involved in EU activities relating to synthetic biology (ERASynBio). In February 2013, a meeting was held in Basel to develop an EU strategy for synthetic biology. A draft white paper is currently being shared with expert groups. The white paper is currently structured around five themes (world-leading and innovative synthetic biology research; responsible development and implementation; a networked, multidisciplinary and transnational community; a skilled, creative and interconnected workforce; and cutting edge and open data and technology), which are similar to the themes in the UK roadmap for synthetic biology. The UK and France have already had considerable input into the white paper. A meeting will be held in Edinburgh at the end of October to finalise the white paper. It will inform the 2nd joint call for synthetic biology, which is likely to launch early in 2014. The 1st joint call, which offered 15.5 M Euro, attracted 54 applications totalling 112 M Euro. This 1st joint call, also funded by

the NSF, attracted over 40 participants from the USA. Funding announcements are likely to follow in early 2014.

Action 11

Richard Kitney reported on a recent fruitful meeting at the Wellcome Trust Genome Campus, Hinxton. There is significant overlap in the biodata of both synthetic and systems biology. When considering the commercialisation of synthetic biology, the SBLC must engage not only with synthetic biology companies, but also with biodata companies working in multiple application areas. There are many bioinformatics companies that conduct bespoke analysis without holding any data themselves, providing the potential for growth of synthetic biology companies.

> ***Action 6: Janet Thornton and Richard Kitney to consult Belinda Clarke, Carol Boyer-Spooner, Chris Warkup and external experts (as required) to systematically identify biodata companies (mainly SMEs).***

Action 12

Noted as done, to be covered in item 5.

Action 13

Lionel Clarke reported that the National Academy of Sciences is still in the process of establishing a synthetic biology forum in the USA, and he continues to engage with them (for example, through the SB 6.0 conference held at Imperial College London in July 2013). The SBLC will be updated as necessary.

Action 14

Paul Gemmill explained that the six academies (the national academies of science and engineering in the UK, USA and China) have identified the need to develop closer links with China, whilst recognising that we are at different stages. David Willetts, currently in China, recently announced a formal programme of interaction between academics based in the UK and China. These UK-China partnering awards mainly foster collaborations between five UK universities (University of Edinburgh, University of Manchester, University of Nottingham, University College London and University of Warwick) and the Shanghai Institute of Biological Sciences, a leading synthetic biology facility in China. It is hoped that these partnering awards will lead to further joint research programmes in the future. Lionel Clarke reported that relationships with colleagues in Japan and Korea are *ad hoc* at present, but may provide more formal opportunities in the future.

Action 15

'SynBio LEAP: the synthetic biology leadership excellence accelerator program' is coordinated by Synberc in the USA. Each year about twenty Fellows – emerging leaders working in diverse areas of biotechnology – are selected to participate. The program is centered on a weeklong in-residence leadership workshop where Fellows work together to develop actionable strategies to address their top challenges for the practice of synthetic biology, under the guidance of world-class experts across disciplines and sectors. In addition to building a cadre of young professionals taking on leadership roles in the synthetic biology community, LEAP aims to create sustainable tools and mechanisms for engaging a broader range of practitioners in the societal role of biotechnology development. James

Brown explained the background to the programme and that the pilot had been deemed a great success. James acknowledged that elements of both iGEM and Biotechnology YES programmes support the development of similar skills in the UK. However, there are aspirations to either replicate SynBio LEAP in the UK or ideally partner with Synberc to gain from their experience and extend the programme to the UK.

Action 7: James Brown to review the pilot LEAP programme and offer a proposal for UK SynBio LEAP at the next meeting of the SBLC.

Action 16

The iGEM (International Genetically Engineered Machine) competition is an annual, worldwide synthetic biology competition that enthuses students about synthetic biology and produces valuable research and innovative projects that often continue beyond the competition. Randy Rettberg (Director, iGEM Foundation) is keen to establish an iGEM office somewhere in Europe, possibly in the UK, although the SBLC has not yet received a formal proposal. James Brown will shortly meet with Randy Rettberg to discuss how this could best be achieved. The SBLC must consider the funding and resources required to host an iGEM office in the UK, as well as the potential benefit. It typically costs in the region of £60,000 for each team to compete and attend the jamboree, which can be a barrier to participation. A UK-based competition might reduce the entry cost for UK teams and help widen participation not only amongst University students, but potentially also A-level students. An office would also provide improved physical access to the DNA parts, which could benefit the wider UK synthetic biology community. The SBLC noted that iGEM is an important educational tool, supporting the development of many transferrable skills. iGEM currently sits outside the university curriculum (although both students and advisors invest a lot of time in each project), but the development it fosters in students is remarkable, so we should consider using the format to strengthen the UK synthetic biology research base. iGEM produces a specially trained workforce, many of whom continue to work in the field of synthetic biology (for example, studying for a PhD or establishing a start-up company based on an iGEM project). There are plans for the recently announced IKC, SynbiCITE, to host an iGEM 'basecamp' to support this effort (see update under item 3).

Action 8: James Brown to update the SBLC on iGEM discussions with Randy Rettberg and the IKC. If appropriate, a proposal for a UK iGEM office will be circulated and discussed at the next meeting of the SBLC.

Action 17

Noted as done. James Brown explained that this is the first open meeting of the SBLC and, as such, we've learned a lot during the process. The SBLC is committed to being transparent and approachable. The venue selection was constrained by both budget and the availability of the minister (who was unfortunately forced to pull out of the meeting at relatively short notice). Ideally, we would have liked a bigger venue to enable those additional five individuals who registered an interest in attending but whom we could not accommodate and have the capacity to accommodate 'walk-in' observers on the day itself. We shall aim to secure the funding for a venue with a capacity for 50-60 observers at the next meeting. The secretariat welcomes both negaitive and positive feedback from the observers.

Action 18

Amy Tayler reported that the next three meetings are likely to fall in March, July and November 2014. Amy thanked those members of the SBLC that have already indicated their availability for the proposed dates. Amy reminded those that have not yet indicated their availability to please do so at the earliest opportunity.

> ***Action 9: SBLC members to indicate their availability for meetings in March and July 2014 on the already circulated Doodle polls, and Amy Tayler to initiate a Doodle poll for November 2014.***

Lionel Clarke thanked the SBLC members for their hard work over the first year of the SBLC, which has given the UK synthetic biology community international visibility. Lionel would like to take the opportunity to assess progress to date, ongoing issues and their relationship to the competencies and experience of those on the SBLC, to determine whether they continue to match the needs of the SBLC for the coming year. Lionel intends to work with Ron Egginton and John Betts (BIS) to review the SBLC. The terms of the review are yet to be finalised, but it will incorporate both external and internal review: questions will be extended to the wider community, and all members of the SBLC will be expected to contribute. This review gives SBLC members the opportunity to raise any issues. Lionel accepts that the SBLC will remain constrained by resources. However, to continue operating efficiently it is anticipated that the SBLC will continue to operate via its relatively small core of standing members, accessing wider expertise within the wider community as necessary directly or within suitably constituted sub-groups. It was noted that other leadership councils are in operation and there is an opportunity for the chairs to share best practise.

> ***Action 10: Lionel Clarke, Ron Egginton, John Betts and the SBLC secretariat to initiate a review of the SBLC and to report back to the SBLC in time for any necessary membership adjustments to be made in advance of the next meeting in March 2014.***

3 Funding World Class Research and Impact

Richard Kitney provided an update on the synthetic biology innovation and knowledge centre (IKC), SynbiCITE, based on the new Imperial West campus. SynbiCITE is funded by TSB, BBSRC and EPSRC, and builds on prior investments in synthetic biology, including the Centre for Synthetic Biology and Innovation (CSynBI, set up in 2009) and the Flowers consortium (set up in 2011), all of which have been funded through national competitions. SynbiCITE's strategy has evolved from the UK roadmap for synthetic biology, focussing on the translation of synthetic biology research to industry. The strategy of SynbiCITE is business-led by a professional industrial management board, on which the funders also sit. In addition to the five principal industrial partners and 35 SME partners, SynbiCITE has 18 academic partners and regional government partners, although it important to note that SynbiCITE is inclusive, not exclusive and has an open door policy. Responsive innovation is key to the IKC and is driven through the participation of the BIOS Centre, King's College London (including Clarie Marris) and the Innogen Institute, University of Edinburgh (including Joyce Tait). SynbiCITE aims to develop an iGEM 'basecamp' within the IKC to support all UK-based iGEM teams (see update under item 1, action 16).

Paul Gemmill gave a short update on research council activities, to complement paper 2. The recent call for multi-disciplinary Synthetic Biology Research Centres (SBRCs) in synthetic biology, which has a budget of £40 M, attracted projects valuing £173.2 M. All leading UK centres for synthetic biology are involved in at least one bid. The assessment panel, which is comprised of mainly non-UK experts and includes Sir Roland Jackson (executive chair of Sciencewise and chief executive of the British Science Association) and Dr Françoise Roure (chairperson, Technology and Society Committee, French High Council for Economy, Industry, Energy and Technology), will meet in early November 2013. Responsible innovation is at the heart of the assessment procedure Sir Roland and Dr Roure will specifically assess the potential ethical and social impacts of each proposal. Formal announcements are likely to follow at the start of December at the earliest. The call has attracted a lot of very good quality applications, many of which the panel is likely to recommend for funding. The funders and assessment panel will together apply a portfolio approach to ensure the awards cover different aspects of synthetic biology. A second phase of the competition is likely will follow in 2014.

Secondly, the recent EPSRC call for doctoral training centres attracted more than 350 expressions of interest (four of which focussed on synthetic biology), approximately 170 of which have been invited to submit full proposals (two of which focussed on synthetic biology). The assessment panel meets next week with the intention to make a rapid decision and an announcement in mid-November. If any of the synthetic biology bids are successful, there may be the opportunity to apply for additional capital funding.

The SBLC acknowledged that these activities all come together to support the UK roadmap for synthetic biology. Whilst each competition goes through an independent assessment process, funding bodies actively avoid duplication and together these investments will form a broad and cohesive UK capability. Once the SBRCs are announced, it will be important for the grant-holders to work together with the IKC. In 2007, BBSRC, EPSRC, ESRC and AHRC funded seven networks in synthetic biology. Funding has now ceased for these networks, although the research councils would like to source additional funding to maintain networking amongst academics.

4 Commercialisation: Synthetic Biology Map and Value Proposition

Belinda Clarke delivered a presentation to complement paper 3. The objective of this work, greatly helped and supported by companies, was to record a baseline, against which the impact of investments in synthetic biology may be assessed on an annual basis to track the growth trajectory and calculate a return on investment. This study focusses on companies and commercial activities and does not include the synthetic biology projects underway at 47 higher education institutes. All data is from the last financial year (2012-2013), with exception of investment data, which is to date. The data is likely to underestimate total synthetic biology activity and economic value, by only including companies whose activities predominantly relate to what may be narrowly defined as synthetic biology.

Major commercial activities in synthetic biology cluster in the South East and around Edinburgh, with a few pockets of activity elsewhere. This is similar to a map for academic activity (see minutes of the previous SBLC meeting for data). Most core commercial activity occurs within SMEs in the business of synthetic biology, plus some ‘tools and services’ companies, and some multi-national companies

have an interest in synthetic biology (although figures for investment are hard to unpack). The collective synthetic biology turnover for 2012-2013 is £8M. Last year, these companies together invested >£2.3 M of their turnover in synthetic biology R&D. To date, public and private investments total £14.3 M and £26.1 M, respectively. The public investment includes funds from TSB, Scottish Enterprise and the EU. The private investment is mainly SMEs that have attracted investment for growth. Approximately 300 jobs (including 50 part-time positions) are attributed to synthetic biology activity, with a combined annual salary of £10.7 M. Salary bands are lower than expected, although many SMEs offer their staff equity in the company. Most companies appear to do their training in-house, with only £72,000 spent on external training, not all of which is specific to synthetic biology but developing more general skills needed in businesses. There are lots of UK and international collaborations with academics and other companies. Many SMEs collaborate with their local university, particularly if they are spin-outs. Interestingly, the majority of industrial collaborations are with overseas collaborators rather than with others based in the UK. Economic development is often facilitated by clusters, but not many synthetic biology companies are working with their neighbours in the UK. Moving forward, the IKC will facilitate industrial collaboration with the UK, Europe and USA. Most customers are based in the UK, followed by USA and Europe. The supply chain data demonstrates that equipment and consumables are usually purchased in the UK, but <25% of technical service spend is spent in the UK. Companies tend to outsource gene synthesis to China, USA and Germany. If the UK were to have greater capability for gene synthesis, we could keep more of this vital activity within the UK. 2012 saw the arrival of seven new start-up companies, four of which were spin-outs from universities. All the SMEs consulted in the study use UK R&D tax credits.

The SBLC noted that the Science and Innovation Network (SIN) has also been consulted on the role of synthetic biology in each country, the results of which are currently being collated.

> ***Action 11: Ron Egginton and John Betts to share the outputs of the SIN network report before next SBLC meeting.***

5 Standards and the EU workshop: IP, Standards and Regulation

Richard Kitney briefly outlined the process of building sections of bacterial DNA into a biopart, and the successive steps required to insert this into a plasmid, and thereby into a target host organism, followed by characterisation of the response. Standards can facilitate systematic design of bioparts (modularisation, standardisation, characterisation) to control complexity. Standard parts make standard devices, which can be combined to make systems. Standards also enable efficient workflow for data exchange and the reuse of synthetic biology engineering knowledge.

ST-FLOW is a collaborative EU/US project on standards (funded by FP7). The grant-holders are working closely with colleagues at BSI to develop standards to better facilitate the use of synthetic biology as a technology platform for use in a variety of applications to develop products for the market. Togther, they hope to develop international standards for synthetic biology to be approved by the ISO. Three technical standards are currently under development:

DICOM-SB: DICOM is already an internationally successful standard in biomedicine (eg: standardising colours and metrology). A synthetic biology extension will be added to DICOM, making DICOM-SB. A

web-based information system in under development, which will modify the data model to use images, biopart data, design notes etc. Data and metadata (such as details of how an experiment was conducted) can be entered onto the data platform.

Synthetic Biology Open Langauge (SBOL): SBOL is an international effort, starting at the University of Washington and now involving the Flowers consortium (comprising five UK universities). SBOL is compatible with DICOM-SB and enable gene circuits to be defined.

JBEI (Joint Bioenergy Institute): JBEI's standards define how to efficiently construct DNA circuits, manage distributed repositories of bioparts and share characterisation data between labs/institutions.

Closely related to these standards is *SEVA* (Standard European Vector Architecture), which defines standard plasmids (into which parts can be inserted) and the associated computer-aided design (CAD).

Ben Sheridan explained that none of the above standards are yet readily available, published nor accepted. BSI aims to develop these standards to be accepted at ISO level, which will further demonstrate UK leadership in synthetic biology. Standards should not be developed in isolation in the UK alone, but developed with the rest of the world with the aim to help progress the synthetic biology field across the globe. It is also recognised that other advances are required to move the technology forward (eg: improvements could be made in human-machine interaction). Standards should be recognised as enablers of R&D, not constraints. Standards and regulations are closely related. Standards are an example of an industry best practise and are not obligatory in themselves. However, a standard can be incorporated into a regulation. Standards are flexible and are regularly reviewed and updated through a formal process (for example, DICOM has evolved a lot since it was originally built by the academic and industrial community). Governance can be built into a standard.

Lionel Clarke summarised the very recent EU workshop on synthetic biology: IP, standards and regulatory issues, which had representatives from across Europe and the USA. The workshop was led by Professor David Castle (Innogen Institute, University of Edinburgh), who introduced the IP issues (as presented at the last SBLC meeting). One of the many issues identified during the workshop is the lack of standards to measure the quality of DNA parts, which make it difficult to quantify performance and compare parts. The workshop was extremely constructive, the outputs of which will be complied with those from the previous two workshops for further analysis. Those involved in the workshop will be invited to help shape the report. The SBLC will consider how the SBLC might address some of the issues identified.

Ben Sheridan described a consensus-building process that could be used to explore the areas of synthetic biology in which we need standards: a representative group of stakeholders will be brought together and the public will be invited to comment. BSI have a duty to take those comments into account. Areas for consideration include both technical and behavioural standards. A stakeholder meeting is likely to take place in January 2014.

Action 12: At the next SBLC meeting, Lionel Clarke to report on IP issues and Richard Kitney to report on standardisation issues arising from the three workshops held in 2013.

6 Responsible innovation, Risk Governance and Dialogue

Joyce Tait delivered a presentation to compliment paper 4. Whilst challenging and complex, a governance sub-group has the opportunity to address issues associated with innovation, synthetic biology being just one example. The paper focusses on a balanced, open and adaptive process in which new technologies can be captured by existing regulatory mechanisms, whilst in turn the regulatory system should be capable of adapting to the properties of emerging technologies. Current regulatory systems are not always adaptive (eg: the regulations for drugs that are being applied to the development of stem cell technologies are not adapted to the requirements of the technology). Regulations should support innovations that can deliver public benefits. The proposed process brings together three constituencies: scientists and innovators; policy makers and regulators; and citizens and stakeholders, each of which will interact with the others. The aim is to balance the interests and values of all.

Scientists & Innovators: Synthetic biology is funded from a variety of different sources, has a broad range of potential applications, and has the potential for both incremental and radical outcomes. The ideal regulatory framework should not necessarily block the development of a technology if it could address a major public need: the projected risks and benefits should be balanced. A regulatory framework could take an adaptive approach to different potential application areas. A creative approach is required to develop future value chains.

Policy makers and Regulators: Different approaches could be taken for early research and downstream applications and innovations. As above, both incremental and radical outcomes should be considered. This group could contribute on the appropriate choice of regulatory precedents and help regulators and policy makers understand the implications of their decisions for innovative capacity. This group will also consider how current regulatory approaches can be more adaptive to deliver public benefits from synthetic biology.

Citizens and Stakeholders: This group should include the full range of stakeholders relevant to each initiative, comprising citizens, interest groups, industry, scientists, policy makers, and regulators. The aim is to have a dialogue about everything related to synthetic biology, including governance, science, innovation, societal concerns and public benefits. This group should take account of the existing context for a dialogue, including previous framings of related technologies.

Two types of regulation are proposed: (i) process based regulation for scientific research, in which the public must engage, and (ii) product based regulation, involving a larger range of stakeholders and to which downstream regulations might be applied.

The suggested activities for the proposed sub-group include: (i) stakeholder engagement and communication, contributing towards building a new consensus for safe delivery of the benefits from synthetic biology and maximum value for money from the UK in basic science, and (ii) comment on national and international aspects of regulation with a view to considering how the SBLC can best contribute to decision level at each level.

A membership of up to 20 has been agreed by the SBLC and will be published once membership is confirmed. Others members of the community may be involved on an *ad hoc* basis.

The SBLC is committed to responsible research and innovation. This proposal suggests that the SBLC needs to consider governance, regulation and engagement too, which also need to be responsible. This paper will be sent to the members of the sub-group (once confirmed) for comment.

During the resultant discussion, the SBLC recognised the importance of open dialogue regarding synthetic biology, and intends to build on BBSRC's continuing activities. The proposed sub-group will have access to a wide network and the suggested activities aim to engage with various different 'publics' in effective and meaningful ways.

Regulations can validate and quality-mark a product. However, the SBLC recognises that current regulatory frameworks that apply to synthetic biology in the UK and EU are very complex. The chief scientific officer has regular meetings with the chairs of the relevant regulatory committees, which play an advisory role. However, the regulatory framework is open to interpretation by lawyers. It is important that regulators understand how their regulations might fit into synthetic biology, so they can determine whether to apply existing regulations or to adapt them to create new ones. The Human Fertilisation and Embryology Authority (HFEA) is a good example of an adaptive regulatory body. The SBLC discussed the value of a sector-based approach: regulation and governance of synthetic biology must take account of the sector in which the technology is being applied. The regulatory framework must be independent from innovation: regulators must base their decisions on fact and should not be influenced by any perceived limit on future innovation or profitability. It will be the job of the SBLC, not the regulators, to consider whether regulations are being interpreted in the right manner. The SBLC intends to engage with those representing the regulators, but the regulators will still act independently.

Synthetic biology is both multi-disciplinary and multi-dimensional, and the UK benefits from a number of discrete groups in both academia and industry. The role of the SBLC covers both communication and integration: to bring together these groups to identify potential areas of concern, ask questions, and guide timely discussions about issues that may affect synthetic biology in the future (eg: standards).

> ***Action 13: Joyce Tait to (i) finalise the membership of the proposed sub-group, (ii) engage with the confirmed members to finalise the proposed activities, and (iii) meet with the sub-group to craft a firmer agenda of activity.***

7 Q&A and Discussion

Three questions were submitted by observers in advance of the meeting. The chair invited these observers to ask their questions.

Paul Goddard, Protein Tech Ltd

Paul Goddard first commented that it can take a long time for even simple technologies to find their most useful applications (eg: wheels, invented in 4,000 BC were not put on suitcases until the 1970s), before asking his question:

> *Most texts define technology as 'the application of scientific knowledge to practical projects.' This reflects widespread acceptance of the so-called Baconian model: i.e. academic discovery leads to applied science/technology leads to real-world practice. However, many modern-day commentators such as Kealey, Scanton and Taleb argue that most industrial innovations are not realized by scientists but by hobbyists and 'geeks' and that with one or two high-profile exceptions (e.g. the atom bomb) history in fact shows the Baconian model to have proceeded for the large part in reverse. In light of these theories, what are the thoughts of the SBLC with respect to the UK's capacity to commercialize synthetic biology, given the nation's well-publicized academic prowess but relative paucity of SMEs?*

The SBLC acknowledges that the UK has not been as effective at commercialisation as our American counterparts (although last year the World Economic Forum reported the UK science base second behind Switzerland at translating knowledge to commercial exploitation). Traditionally, UK Government has been very effective at supporting academic research, but has tended to 'push fledgling technologies out of the nest too soon': while it is important to ensure the strength and depth of the science base, the market has been expected to adopt these new technologies while they are still too uncertain. The activities in the Synthetic Biology Roadmap create a framework to give start-ups and companies greater support (eg: the SBLC and the synthetic biology special interest group have been established, and the Technology Strategy Board has identified synthetic biology as a potential opportunity and provided specific funding opportunities). The Baconian model should go both ways: we want companies in the UK to both benefit from, and stimulate, academic developments in synthetic biology.

Regulations can mean that any innovation in the life sciences is lengthy and costly. Whilst multi-national companies can afford to meet these costs, they are prohibitive for SMEs, unless the companies are bought out by multi-national companies. This situation leads to many incremental innovations. To develop disruptive technologies, the business model needs to change.

New technologies have the potential to change societies. It is not the Government's role to pick winners, but to support technology development. We don't yet know all that will arise from synethtic biology, but there is the potential for it to be applied in lots of ways, in both the short and long term, providing employment opportunities in the UK.

Linda Brooks, Life Technologies Ltd

> *Does the leadership council have a view/ strategy on how to get support from suppliers, companies to all the initiatives which are being kicked off?*

The SBLC supports an interconnected framework in which companies can thrive. Public meetings of the SBLC are just one example of bringing together different synthetic biology stakeholders. The synthetic biology special interest group, with over 750 members, is forming a community in which others can see what others are doing and make better connections. Special interest groups and the

Knowledge Transfer Networks are there to connect people by forming communities, facilitating events and making introductions. Innovation happens at the interfaces of different disciplines, when people from different backgrounds are brought together. TSB competitions support collaboration (both business-to-business as well as business-to-academia), and can involve vertical supply chain consortia, from technology providers to retailers. The Innovation and Knowledge Centre will bring together academia and industry (not only those companies represented on the IKC Industry Strategy Group, but also with a wider network of both multi-national companies and SMEs). BBSRC has a similar philosophy regarding the multi-disciplinary research centres in synthetic biology: encouraging the involvement of companies without prescribing how it should be done. As yet, we don't know the application areas in which synthetic biology will have the most impact. The Industrial Biotechnology Leadership Forum (IBLF) is working towards identifying where industrial biotechnology can be used and raising the awareness of application sectors to IB to help realise its potential. The SBLC has the same role with synthetic biology: to raise awareness and the profile of synthetic biology.

> *Any thoughts on setting up a central clearing house for the IP that will be created in the coming time?*

This year, the SBLC and the Synthetic Biology Special Interest Group (SynBio SIG) have been involved in three workshops exploring regulations, standards and intellectual property issues relating to synthetic biology, the most recent of which took place last week. A central clearing house has been discussed, although it is a complicated area that will benefit from some serious consideration. The SBLC will see whether progress can be made as and when the points arising from the workshop are further distilled.

Helena Paul, EcoNexus

> *In the public dialogue on synthetic biology for which I was part of the oversight group, fundamental questions came from members of the public:*
>
> - *What is the purpose? Why are you doing it? What are you going to gain? What else will it do? How you know you are right?*
> - *Other questions were: What are the alternatives to this? What other ways are there of doing it?*
> - *One group said: an impact assessment on how will it affect society should be required before research goes ahead.*
>
> *However the tone of the governance paper seems strongly biased towards commercial development of the technology in advance of further discussion. Also the paper clearly implies that discussion must avoid arousing the opposition that previous technologies have met with, with the underlying assumption that this opposition is not well-founded. Could the drafters of the paper please explain why this is, and how they plan to address the questions raised by the public above? How do you recruit people and what are they responsible for?*

The SBLC acknowledged that these are deep and important questions, and it is difficult to obtain a complete range of views. These issues were debated at considerable length during the development of the Synthetic Biology Roadmap, and they are reflected within the roadmap. Responsible Innovation (RI) is now built into the relevant calls and competitions administered by the Technology Strategy Board and the research councils: applicants are specifically asked what consideration they

have given to these questions. Each synthetic biology project funded by the Technology Strategy Board is also assigned a RI mentor. Grant-holders are also invited to attend RI workshops, in which they have been very willing to engage and participate. There is still more for us to do. We are listening to the responses, reflecting upon them, ensuring that RI is built in to projects and giving balance to the process. We want to learn from the process to get to a place where benefits are consistently delivered.

The SBLC encourages ongoing discussion. There are some areas where you can do a public impact assessment today, but also other areas where we don't yet know enough to do an impact assessment. Some sectors are further ahead than others, and timing is very important. It is important that each sector has the right dialogue. The proposed activities of the sub-group are not intended to be biased towards commercialisation per se, but delivery of benefits from innovative technologies is a key objective, and commercial mechanisms that will help deliver such benefits are an important factor to be considered. The aim is to help ensure that benefits can be delivered with appropriate constraints in place.

The SBLC wants activities within the UK to lead the way in a responsible and ethical fashion. There are already examples of synthetic biology approaching the market (eg: synthetic artemisinin production for the treatment of malaria, although Helena Paul commented that a synthetic compound may not necessarily deliver all the benefits of a plant extract).

The SBLC recognises that there is a need for continuing reflection. The roadmap makes a start, and these public meetings are the next stage of the process. The motivation of the SBLC is to have genuine engagement. The synthetic biology dialogue was a really good start, and we want to keep it going.

The question '*Is there another way of doing this?*' is very interesting. In some case, other technologies may indeed be available and have been used for many years. However, for historic reasons they may themselves be unregulated, and their risks unassessed. Greater reliability, additional benefits and improved cost effectiveness are all reasons why the development of a new technology may be considered desirable. A balanced and proportionate approach should be applied.

The chair then invited observers to ask additional questions.

Hillary Sutcliffe, MATTER

Hillary supports Helena Paul on a RI working group. They have tried to learn lessons from nanotechnology, in which a distinction has been made between those things that cause concern (eg: single molecules) and those things that don't (eg: emulsions). Hillary asked whether the SBLC has a plan to consider classifications to allow stakeholders, regulators and business to understand what should be addressed and prioritised.

In response, it was suggested that products under development that might have a huge benefit over an existing technology could be fast-tracked.

Hillary suggested that concerns about nano-safety are too broad and should have focussed on the dangerous issues: a slow-track is as important as a fast-track.

It is fully recognised that specific applications will be assessed within the regulatory frameworks that apply, and that the rate of progress will depend on the development of sufficient suitable evidence that will be evaluated on a case by case basis.

Tim Dafforn, University of Birmningham
At a recent meeting of the Bioprocessing Research and Industry Club (BRIC), companies described the design-build-test cycles that have been running for 20 years, which is a long way ahead of some of the technology discussed in this meeting. When asked about this meeting, the company representatives were ambivalent or negative. Tim asked whether the SBLC has representation from the bioprocessing sector, from which both parties could benefit: the sector may have already solved some of the problems under discussion by the SBLC, and the sector may have systems with which the SBLC could help.

The chair noted that the SBLC works closely with the Industrial Biotechnology Leadership Forum and this may provide a suitable channel to follow up such issues

> ***Action 14: Belinda Clarke, James Brown and Carol Boyer-Spooner to discuss engagement with the bioprocessing sector with Tim Dafforn.***

Mark Morrison, Institute of Nanotechnology
Mark asked for the SBLC's view or vision of how an international dimension of synthetic biology can be addressed.

From early 2014, Horizon 2020 will provide a host of opportunities. In comparison to Framework Programme 7, Horizon 2020 has increased industrial emphasis. The Research Councils are also working more closely with Technology Strategy Board and UKTI, which are all linked through a single Government department (Business, Innovation and Skills). The 2nd joint call for ERASynBio is also under development, which may provide additional opportunities.

The KTNs and the SynBio SIG are agnostic about the origin of the background science to be exploited in the UK. International connections can be identified, but the mechanisms to fund international collaborations are not always in place. The Technology Strategy Board has signed a memorandum of understanding with Innovation Norway to fund collaborations on industrial biotechnology between the UK and Norway. This model could be applied in other technology areas with other countries. The recent agreement with China to establish exchange studentships in Synthetic Biology is another example of ongoing initiatives to futher build such international dimensions.

Paper 1 demonstrates interactions with US colleagues. Amanda Collis (on secondment from BBSRC to Sciences Innovation Network, Boston and SBLC member) also keep us in touch with activities in the US.

8 Items to note

Belinda Clarke described the upcoming Technology Strategy Board competition entitled 'Tools and Services for Synthetic Biology,' which will open on 18th November 2013. The total funding pot, currently estimated at £3.5 M, is likely to increase. The briefing document will be circulated amongst the SBLC when the additional funding is confirmed.

> ***Action 15: SBLC secretariat to circulate the final briefing document to SBLC members as and when it is agreed.***

Carol Boyer-Spooner highlighted that the Chemistry Growth Partnership, launching on 22nd October 2013, may provide opportunities for synthetic biology engagement.

Lionel expressed his hope that throughout the course of the day the observers had witnessed the breadth and depth of the items that are addressed by the SBLC. The SBLC aims to plan for success, whilst putting in place the necessary safeguards and checks. Lionel encouraged observers to contact the SBLC with feedback and any unanswered or additional questions. We intend to learn from hearing what we could have done better, and questions/thoughts/ views will be accommodated as appropriate. The sub-group and SynBio SIG are both likely to organise additional activities, in which the observers are encouraged to take part. The next (closed) meeting of the SBLC will be in March 2014. SBLC members and observers are welcome to suggest potential agenda items.

> ***Action 16: SBLC secretariat to work with Paul Gemmill to initiate a feedback mechanism for SBLC members and observers to report on this first open meeting of the SBLC, to include the address for the SynBio SIG and the SBLC website.***

The chair thanked everyone for their participation in this first open meeting of the SBLC and formally closed the meeting.

Summary of Actions from 3rd SBLC meeting (17th July 2013)

#	Action	Owners (participants)	Deadline
1	Minutes from 2nd meeting of SBLC (agreed) to be uploaded to SBLC pages on _connect	Amy Tayler	ASAP
2	Data from survey to establish the appetite for investment in synthetic biology to be shared with the SBLC	Amy Tayler (Belinda Clarke)	ASAP
3	Biosciences KTN to consider running a BioVentures event focussed on synthetic biology. If approached, SBLC members to pass the details of interested investors to James Brown	James Brown (all)	On-going
4	Dropbox folder to be set up for collaboration amongst the SBLC members	Amy Tayler	ASAP
5	Highlight synthetic biology to the various sector directors within UKTI.	Janet Bainbridge	On-going
6	Revisit data from roadmap workshops, Syn Bio SIG questionnaire and TSB data (see action 7)	James Brown	On-going
7	Agree joint statement of recent activities, case studies, value proposition and joint synthetic biology logo for publication on SBLC website (see action 6)	James Brown (Ron Egginton, Belinda Clarke, Richard Kitney, Paul Gemmill, Janet Bainbridge – to be signed off by Lionel Clarke)	ASAP
8	Map of the UK synthetic biology community and outputs from the synthetic biology valuation exercise to be presented at the next meeting of the SBLC	Belinda Clarke	16th October 2013 (next meeting)
9	Stakeholder engagement and regulation and governance issues sub-groups to meet and to involve John Betts (BIS) from September 2013	Joyce Tait (Janet Bainbridge, Chris Warkup, Ron Egginton, Paul Gemmill, Richard Kitney, Lionel Clarke, Sharmila Nebhrajani)	ASAP
10	SBLC to work with Andy Boyce (ERASynBio) to contribute to strategic white paper in advance of 2nd joint call from ERASynBio	Paul Gemmill (Lionel Clarke)	On-going
11	To discuss commercialisation efforts in biodata	Janet Thornton and Richard Kitney	On-going
12	Outputs from the UK and six-academies IP meetings to feed into the arrangements for the European IP meeting in October 2013	Lionel Clarke (Richard Kitney, James Brown, Amy Tayler)	On-going
13	Explore opportunities for the SBLC to partner with the NAS forum in the US, to include case studies and the sharing of best practise with regard to IP and academic-industry collaborations	Lionel Clarke	On-going

14	Explore opportunities for the SBLC to interact with China and possibly Japan and Korea	Lionel Clarke	On-going
15	Explore US programmes 'iCorps' and 'SynBio LEAP' and consider the value of bringing them to the UK	James Brown	On-going
16	As and when it is received, respond to Randy Rettberg's proposal to locate an iGEM office in Europe or the UK.	James Brown (Richard Kitney Ron Egginton)	On-going
17	Speak to FSA and Defra re: arrangements for open meetings	Amy Tayler and James Brown	ASAP
18	Arrange dates for 5^{h} and 6th meetings of the SBLC, March and July 2014	Amy Tayler	ASAP

Summary of actions arising from the 4th meeting of the SBLC (16th October 2013).

Action 1: Janet Bainbridge and the UKTI marketing team to consult the SBLC on key messages regarding synthetic biology and the GREAT campaign.

Action 2: The resultant UKTI GREAT marketing materials to be circulated to the SBLC via the secretariat.

Action 3: Revisit the outputs from the roadmap workshops and report back at next SBLC meeting (James Brown)

Action 4: SBLC secretariat to upload paper 2 to the SBLC pages of the SynBio SIG website, and to convey the information in a more digestible form.

Action 5: Explore opportunities to (i) brand the SBLC and (ii) badge UK synthetic biology activities, and report back at next meeting (James Brown, Janet Bainbridge and Ron Egginton).

Action 6: Janet Thornton and Richard Kitney to consult Belinda Clarke, Carol Boyer-Spooner, Chris Warkup and external experts (as required) to systematically identify biodata companies (mainly SMEs).

Action 7: James Brown to review the pilot LEAP programme and offer a proposal for UK SynBio LEAP at the next meeting of the SBLC

Action 8: James Brown to update the SBLC on iGEM discussions with Randy Rettberg and the IKC. If appropriate, a proposal for a UK iGEM office will be circulated and discussed at the next meeting of the SBLC.

Action 9: SBLC members to indicate their availability for meetings in March and July 2014 on the already circulated Doodle polls, and Amy Tayler to initiate a Doodle poll for November 2014.

Action 10: Lionel Clarke, Ron Egginton, John Betts and the SBLC secretariat to initiate a review of the SBLC and to report back to the SBLC in time for any necessary membership adjustments to be made in advance of the next meeting in March 2014.

Action 11: Ron Egginton and John Betts to share the outputs of the SIN network report before next SBLC meeting.

Action 12: At the next SBLC meeting, Lionel Clarke to report on IP issues and Richard Kitney to report on standardisation issues arising from the three workshops held in 2013.

Action 13: Joyce Tait to (i) finalise the membership of the proposed sub-group, (ii) engage with the confirmed members to finalise the proposed activities, and (iii) meet with the sub-group to craft a firmer agenda of activity.

Action 14: Belinda Clarke, James Brown and Carol Boyer-Spooner to discuss engagement with the bioprocessing sector with Tim Dafforn.

Action 15: SBLC secretariat to circulate the final briefing document to SBLC members as and when it is agreed.

Action 16: SBLC secretariat to work with Paul Gemmill to initiate a feedback mechanism for SBLC members and observers to report on this first open meeting of the SBLC.