

February 2019

BIA Advisory Committees

Review of 2018 activity and 2019 priorities



Cell and Gene Therapy Advisory Committee (CGTAC)



Chair:

Sven Kili, Sven Kili Consulting

BIA Secretariat:

Peter Wasson

CGTAC 2018 review

Connect:

- Contributed to BIA events e.g. UK Bioscience Forum
- Contributed to international Cell and Gene Therapy events/engagement
- Recruited more members

Inform/Support:

Informed BIA policy work/engagement on:

- Genome-editing
- The Nagoya Protocol through the BIA Nagoya Cross-Committee Working Group
- Implementation of the AAR/AAC
- Innovate UK issues, including roll-out of Advanced Therapies Treatment Centres

Expert advice:

- Developed a plan for contributing to the access and regulatory actions in the Advanced Therapy Manufacturing Taskforce Action Plan, in collaboration with MAC and RAAC
- Produced BIA's Cell and Gene Therapy Explainer

CGTAC 2019 outline



Connect:

Promote UK excellence in cell and gene therapies both internationally and with UK policy-makers:

- Via partnerships with the Alliance for Regenerative Medicine and Phacilitate
- Using the BIA's Cell and Gene Therapy Explained document

Inform/Support:

BIA policy work on:

- Industrial Strategy and implementation of the Life Sciences Sector Deal, keeping Cell and Gene Therapy central to Industrial Strategy, especially in relation to innovation policy and support
- NHS access and reimbursement for cell and gene therapies including responding to potential opportunities presented by the Accelerated Access Collaborative and keeping abreast of the Advanced Therapy Treatment Centres
- Use of NHS patient data
- Genome-editing

Expert advice:

- Input to the development of measurements and standards for cell and gene therapies via the MHRA, (including NIBSC), the National Measurement System (including LGC), the British Standards Institute, the Standards Coordinating Body and FIRM
- Respond to increasing government interest in cell and gene therapies and feed in to government-led activity as appropriate

Engineering Biology Advisory Committee (EBAC)



Chair:

Tim Brears, Evonetix

BIA Secretariat:

Eric Johnsson

Connect:

- Represented the UK engineering biology sector at BIA CEO & Investor Forum and Bioscience Forum, and SynBioBeta and iGEM in the US
- New committee members include: Evonetix, CustoMem, SYNBIOCHEM Centre for Synthetic Biology Research
- Hosted inaugural Christmas drinks

Inform/Support:

- Supported BIA's policy and public affairs work: Parliament Day, Industrial Biotech Parliamentary breakfast and Parliamentary briefing on genome editing
- Supported engineering biology Wave 3 Expression of Interest for the Industrial Strategy Challenge Fund (ISCF)

Expert advice:

- Increased investor awareness through attendance at BIA CEO & Investor Forum and through the BIA explainer and video on engineering biology

Connect:

- Represent the engineering biology sector at BIA and external events, e.g. Bioscience Forum, SynBioBeta, iGEM and SynbiTECH
- Continue to attract new committee members by promoting the breadth and depth of the sector
- Coordinate activities with the Synthetic Biology Leadership Council, SynbiCITE, research centres and wider community
- Host networking drinks

Inform/Support:

- Support BIA lobbying activities, including Parliament Day, engagement on relevant Industrial Strategies, the Industrial Strategy Challenge Fund and wider UKRI engagement around the 2019 Spending Review

Expert advice:

- Increase investor engagement with UK engineering biology, e.g. at BIA's CEO & Investor Forum, Strategic Technologies showcase and similar events
- Promote sector through Parliamentary roundtable around the BIA Eng Bio Explainer

Finance and Tax Advisory Committee (FTAC)



Chair:

Colin Hailey, Confluence Tax

BIA Secretariat:

Dr Martin Turner

Connect:

- Engaged with non-members inside and outside the sector including the finance and investment community
- Invited a guest speaker to (nearly) each meeting
- Hosted inaugural Committee Drinks and a finance strategy dinner

Inform/Support:

- Continued to generate ideas and support the BIA in relevant consultations from government and other bodies, including HM Treasury & HMRC on EIS fund structures, entrepreneurs' relief, and intangible assets
- Monitored the implementation of relevant sections of Patient Capital Review

Expert advice:

- Kept BIA members informed about developments, best practice and their responsibilities, with a guide on the Patent Box and another on R&D tax credits
- Blog on changes to entrepreneurs' relief

Connect:

- Recruit new members to expand the expertise and breadth of the committee
- Continue to invite guest speakers and host Committee Drinks

Inform/Support:

- Lead on engagement with HMT and HMRC on changes to R&D tax credits and entrepreneurs' relief that could be detrimental to the sector, and on the rewrite of the BEIS R&D guidelines in collaboration with the British Pharmaceutical Group
- Link with the BIA's wider investor community engagement to support the Patient Capital Review agenda

Expert advice:

- Help BIA members understand new funding opportunities, including the variety of grants available to companies
- Represent the sector at government meetings and forums
- Ensure members are informed about the impacts of Brexit on finance and tax matters

Genomics Advisory Committee (GAC)



Chair:

Adrian Ibrahim, Wellcome Trust Sanger Institute

Vice –Chair:

Anthony Finbow, Eagle Genomics

BIA Secretariat:

Eric Johnsson

Connect:

- Contributed to BIA events, including BIA activity at JP Morgan and BIO and a panel session at the 2018 UK Bioscience Forum
- Met with Genomics England's CEO and COO to inform their business model. Also met with Director of OLS to inform their thinking on genomics and the LSIS

Inform/Support:

Input in to BIA policy work and consultation responses on:

- The use of genomics in the NHS
- The use of patient data and genomic data
- Science and innovation funding
- The LSIS and Sector Deals
- The Future of Surgery

Expert advice:

- Provided content for the BIA's *Genomics Explained* document and video

Connect:

- Engage with the broader UK genomics landscape and recruit more members
- Identify, share intel on and get involved in international opportunities to ensure GAC members' interests are represented at a global level
- Continue to engage with Genomics England but also reach out to other large-scale projects, which GAC members may wish to support or become involved in
- Support BIA events – panel session at UK Bioscience Forum

Inform/Support:

- Input in to BIA consultation responses on relevant policy issues
- Support BIA engagement on the LSIS and Sector Deal – specifically around the delivery of Wave 2 and 3 of the ISCF, including the Digital Innovation Hubs
- Support plans to use the BIA's Genomics Explainer's to engage with key stakeholders

Expert advice:

- Secure and act as SME representation on UK Genomics Board

Intellectual Property Advisory Committee (IPAC)



Chair:

John Murphy, Vectura

Vice-Chairs:

Nicole Jadeja, Fieldfisher; Michelle
Jones, Astex

BIA Secretariat:

Dr Martin Turner

Connect:

- Hosted summer Drinks and Christmas Lunch
- Refreshed membership to ensure equitable representation of BIA community
- Launched newsletter to increase engagement

Inform/Support:

- Supported the BIA in relevant consultations and Brexit activity, including looking at post-Brexit opportunities, future trade policy, and continued monitoring implementation of the UPC
- Supported BIA submission to the Supreme Court review of ICOS vs Actavis

Expert advice:

- Provided advice to the IPO on CJEU case referrals
- Represented the sector at stakeholder meetings on international IP harmonisation and an IPO B2B licensing toolkit
- Monitored other international IP policy developments

Connect:

- Engage the wider BIA community by inviting speakers to share their company's IP interests & issues, and by developing the committee newsletter
- Continue to host Summer Drinks and Christmas Lunch

Inform/Support:

- Help shape the BIA's trade policies to inform government trade deal negotiations
- Support the BIA in relevant consultations and Brexit activity
- Represent the sector in the courts, monitor the implementation of the UPC, and contribute to Nagoya activity with EBAC and CGTAC

Expert advice:

- Ensure BIA members are kept informed about developments in IP law and policy, including the impact of Brexit, through briefings and blogs
- Continue to provide advice to the IPO on CJEU case referrals
- Represent the sector at national and international meetings and fora

Manufacturing Advisory Committee (MAC)



Chair:

Stephen Ward, Cell and Gene Therapy Catapult

Vice-Chair:

Kit Erlebach, Fujifilm Diosynth Biotechnologies

BIA Secretariat:

Netty England

Connect:

- 30 members spanning biologics, vaccines and cell & gene therapies cross-pollinating expertise and best practice through networking and site visits
- Networked through committee drinks and continued engagement with KTN

Inform/Support:

- Delivered another successful programme for the 2018 bioProcessUK conference.
- Contributed to the 2018 UK Bioscience Forum

Expert advice:

- Key pan-industry stakeholder within Life Sciences Industrial Strategy:
 - Proposed bioproduction initiatives for Industrial Strategy Challenge Fund and MMIP Technology & Innovation workstream
 - Major role in delivering skills recommendation from the MMIP Advanced Therapy Manufacturing Taskforce Action Plan; supported delivery of standards and access actions with CGTAC and RAAC
- Based on the great success of cohort 1, initiated cohort 2 of next generation of bioproduction leadership programme.
- Represented BIA at the MHRA GMP/GDP consultative committee meetings

MAC 2019 outline



Connect:

- 31 members spanning biologics, vaccines and cell & gene therapies cross-pollinating expertise and best practice through networking and site visits
- Network through site visits, seminars, committee socials and engagement with KTN

Inform/Support:

- Deliver another successful programme for the 2019 bioProcessUK conference
- Contribute to the 2019 UK Bioscience Forum

Expert advice:

- Key pan-industry stakeholder within Life Sciences Industrial Strategy:
 - Work with existing Industrial Strategy Challenge Fund investments and influence future investments, aligning with the MMIP T&I workstream
 - Champion life sciences support
 - Major role in anchoring manufacturing of ATMPs for early phase academic-led clinical trials in the UK
 - Skills delivery through successful BIA MAC LeaP initiative and support ISCF funded ATAC programme led by CGT Catapult
- Input into Brexit consultations
- Represent BIA at the MHRA GMP/GDP consultative committee meetings

Regulatory Affairs Advisory Committee (RAAC)



Chair:

Emma Du Four, AbbVie

Vice-Chair:

Andrew Fox, PsiOxus Therapeutics

BIA Secretariat:

Dr Christiane Abouzeid

Connect:

- Reviewed and updated the RAAC Terms of Reference to reflect the broad range of responsibilities and experience of RAAC members
- Continued strong partnership and regular interactions with MHRA, NIBSC and NICE

Inform/Support:

- Shared experience amongst RAAC members and supported Secretariat with BIA submission to MHRA consultation on EU Exit no-deal contingency legislation
- Informed BIA policy work on medicines regulation post-Brexit

Expert advice:

- Partnered with MHRA and provided input into assessment of the practical implications of various options/scenarios for post-Brexit regulatory framework
- Continued positive engagement with MHRA, NIBSC and their representatives including their attendance as guest speakers at RAAC meetings
- Supported BIA/MHRA innovation conference, attended by 200+ delegates across the life sciences sector

Connect:

- Continue to bring together regulatory affairs representatives from the BIA community and use this group as a key touch-point for engagement with key stakeholders, including MHRA, NIBSC and NICE
- Build on existing BIA relationships with other trade associations and partner with EuropaBio and BIO on EU and US regulatory topics of interest to members

Inform/Support:

- Support preparation and delivery of the 2019 BIA Regulatory Conference
- Support BIA policy and engagement with UK Government on regulatory aspects for international trade and research

Expert advice:

- Provide input into BIA work and help shape the post-Brexit UK regulatory framework and MHRA future role as part of the UK innovation ecosystem and at a global level

Science and Innovation Advisory Committee (SIAC)



Chair:

Mark Carver, Consultant

Vice –Chair:

Penny Ward, PWG Consulting

BIA Secretariat:

Netty England

Connect

- Further engagement with CSO community along with continued engagement with CMO community

Inform/Support:

- Supported the delivery of the inaugural BIA CMO Forum in March 2018
- Supported the delivery of a lunch in May 2018 bringing stakeholders together to discuss industry engagement with UKRI

Expert advice:

- Delivered draft paper 'Manufacturing Science for the Health Life Sciences' (interim title) to argue importance of early stage research funding to bioprocessing
- Influenced relevant areas of science policy as Life Science Industrial Strategy and Sector Deals emerged, e.g. long-term funding environment and clinical trials
- Engaged with UKRI

Connect

- Further engagement with CSO community along with continued engagement with CMO community

Expert advice:

- Influence relevant areas of science policy as Life Science Industrial Strategy and Sector Deals emerge, e.g. long-term funding environment and clinical trials
- Support the BIA's Comprehensive Spending Review activities
- Engage with UKRI and champion life sciences support post Brexit

Inform/Support:

- Support the delivery of the CMO “Bench to Bedside” webinar series and session at UK Bioscience Forum
- Support the delivery of a science and innovation based lunch - How can UK biotech work most effectively with UKRI?