

BIA Advisory Committees

Review of 2019 activity and 2020 priorities



- Cell and Gene Therapy Advisory Committee (GCTAC)
- Engineering Biology Advisory Committee (EBAC)
- Finance and Tax Advisory Committee (FTAC)
- Genomics Advisory Committee (GAC)
- Intellectual Property Advisory Committee (IPAC)
- Manufacturing Advisory Committee (MAC)
- Regulatory Affairs Advisory Committee (RAAC)
- Science and Innovation Advisory Committee (SIAC)

BIA Advisory Committees



Forums/Networks:

- Government Affairs Network**
- Women in Biotech**
- China Special Interest Group**
- Rare Disease Industry Group**
- Pensions Working Group**
- Future Trade Working Group**

Cell and Gene Therapy Advisory Committee (CGTAC)



Chair:

Sven Kili, Sven Kili Consulting

Vice-Chair:

Helen Delahaye, Azellon

BIA Secretariat:

Peter Wasson

Connect:

- Promoted UK excellence in Cell and Gene Therapies (CGT) internationally and with UK policy-makers
- Developed partnerships with the Alliance for Regenerative Medicine (ARM), Japan's Forum for Innovative Regenerative Medicine (FIRM) and Phacilitate
- Worked with ARM to develop the evidence on CGT in the UK, publishing the ground-breaking report *Leading Innovation: the UK's ATMP Landscape* with a launch event in London and at a parliamentary reception
- Signed MoU with FIRM and exchanged translated membership directories with FIRM at BIO Japan

Inform/Support:

- Industrial Strategy and implementation of the Life Sciences Sector Deal, keeping CGT central to Industrial Strategy, especially in relation to innovation policy and support
- NHS access and reimbursement for CGT, including responding to opportunities presented by the Accelerated Access Collaborative and keeping abreast of the Advanced Therapy Treatment Centres
- BIA activity on the use of NHS patient data and genome-editing

Expert advice:

- Input to the development of measurements and standards for CGT via the MHRA, (including NIBSC), the National Measurement System (including LGC), the British Standards Institute, the Standards Coordinating Body and FIRM
- Responded to increased government interest in CGT and fed in to government-led activity

CGTAC

2020 priorities



Connect:

- Promote UK excellence in Cell and Gene Therapies both internationally and with UK policymakers
- Build on strong partnerships with ARM, FIRM and Phacilitate and seek opportunities to engage with other coalitions
- Build connections with the regulatory environment, including the MHRA and the British Pharmacopeia

Inform/Support:

- Develop an ongoing report series in collaboration with ARM on the ATMP landscape in the UK to highlight the UK's leading position in CGT
- Contribute to the development of the Innovation Office and the UK's global CGT offering
- Support BIA engagement with Ministers and their advisers, keeping CGT central to government policy

Expert advice:

- Input to the development of measurements and standards for CGT via the MHRA, the National Measurement System, the British Standards Institute and the Standards Coordinating Body.
- Feed into government-led activity related to CGT, such as patient registries, skills and training
- Respond to opportunities to engage on NHS access and reimbursement policies for CGT, including those presented by the Accelerated Access Collaborative, the NICE Methods Review and other programmes

Engineering Biology Advisory Committee (EBAC)



Chair:

Tim Brears, Evonetix

Vice –Chair:

Edward Green, CHAIN Biotechnology

BIA Secretariat:

Eric Johnsson

Connect:

- Represented the UK engineering biology sector at BIA CEO & Investor Forum, Bioscience Forum and BioProcess UK, and at BIO and SynBioBeta in the US
- Grew the committee with new members including the National Physical Laboratory (NPL) and the University of Nottingham
- Hosted networking event

Inform/Support:

- Supported BIA lobbying activities including Parliament Day and Spending Review
- Supported BIA with case studies in the report *Life Sciences: Catalysing Investment and Growth* and in the publication of the summarised Engineering Biology explainer
- Increased investor awareness by organising an engineering biology pitching competition at the Bioscience Forum

Expert advice:

- Led on the BIA submission to the Convention on Biological Diversity (CBD)'s international consultation on digital sequence information (DSI) on the Nagoya Protocol

EBAC

2020 priorities



Connect:

- Represent the UK engineering biology sector at both BIA and international conferences, e.g. CEO & Investor Forum, SynbiTECH and SynBioBeta and organise a session at the Bioscience Forum
- Coordinate activities with stakeholders across the sector, including the Synthetic Biology Leadership Council and the Royal Academy of Engineering
- Attract new committee members and support BIA efforts to expand its membership into green biotech
- Host networking event

Inform/Support:

- Promote the environmental benefits of engineering biology to civil servants, investors, funders and the public to increase awareness of and investment into the sector
- Support BIA lobbying activities, including Parliament Day, the Bioeconomy Strategy and 2020 Spending Review

Expert advice:

- Continue to lead on BIA's efforts to stop the inclusion of digital sequence information (DSI) into the Nagoya Protocol
- Promote sector through Parliamentary event around the BIA Engineering Biology explainer

Chair:

Colin Hailey, Confluence Tax

Vice-Chair:

Vacant

BIA Secretariat:

Dr Martin Turner

Connect:

- Recruited five new members. Engaged with non-members inside and outside the sector including the finance and investment community, invited guest speakers to most meetings and hosted Summer networking event

Inform/Support:

- Successfully campaigned against proposed PAYE cap to R&D tax credits
- Held productive talks with HMRC on tax credits and BEIS R&D guidelines
- Raised the sector's concerns on Enterprise Management Incentives (EMI) valuations and State Aid rules for Innovate UK grants
- Input to BIA Spending Review report

Expert advice:

- Kept BIA members informed about developments, particularly on Entrepreneurs' Relief and the PAYE cap proposal

Connect:

- Conduct a survey of the BIA membership to ensure FTAC is addressing the issues relevant to the sector and recruit new members to expand the expertise and breadth of the committee
- Continue to invite guest speakers to Committee meetings and host networking events

Inform/Support:

- Lead on engagement with the new Government's policy agenda in a way that maximises opportunities for the sector, including changes to Entrepreneurs' Relief and R&D tax credits, and on the rewrite of the BEIS R&D guidelines in collaboration with the British Pharmaceutical Group
- Respond to other government activity as it arises, recognising that the Committee's work is largely reactive in nature.

Expert advice:

- Continue to ensure BIA members are aware of any important tax changes and issues

Chair:

Adrian Ibrahim, Wellcome Sanger Institute

Vice –Chair:

Anthony Finbow, Eagle Genomics

BIA Secretariat:

Eric Johnsson

Connect:

- Recruited many new committee members, including AstraZeneca, IQVIA and Medicines Discovery Catapult
- Continued to engage with Genomics England, including started a positive relationship with the new CEO
- Organised a panel session on commercial genomics at the UK Bioscience Forum

Inform/Support:

- Supported BIA's lobbying activities including Parliament Day, Spending Review and the Life Sciences Industrial Strategy
- Informed BIA submission to a parliamentary inquiry on commercial genomics
- Supported BIA with case studies in the report *Life sciences: Catalysing investment and growth* and in the publication of the summarised Genomics explainer

Expert advice:

- Started engagement with the Royal College of Physicians to coordinate messaging on the use of genomics in the NHS

Connect:

- Grow the committee further and enable SME engagement with big pharma
- Continue to build a positive and productive relationship with Genomics England to enable SME access to data
- Host a panel session at the UK Bioscience Forum

Inform/Support:

- Develop more detailed policy positions on genomics for BIA's lobbying activities
- Support BIA's lobbying activities, including Parliament Day, the Life Sciences Industrial Strategy and the 2020 Spending Review
- Publish a report mapping UK genomics companies and outlining the strength of the sector

Expert advice:

- Influence other stakeholders in the genomics ecosystem, including the Royal College of Physicians
- Secure and act as SME representation on UK National Genomics Board

Chair:

John Murphy, Vectura

Vice-Chairs:

Nicole Jadeja, Pinsent Masons;
Michelle Jones, Astex

BIA Secretariat:

Dr Martin Turner

Connect:

- Hosted summer and Christmas networking events
- Held member presentations to learn more about the membership
- Expanded newsletter mailing list to increase engagement

Inform/Support:

- Supported the BIA in responding to no-deal statutory instruments.
- Represented the BIA at bilateral meetings with the IPO and on government working groups on future trade policy
- Monitored and responded to the EU IP review
- Responded to a consultation on greater access to pro bono advice for biotech start-ups and another on client-attorney privilege

Expert advice:

- Published a guide for BIA members on the Supplementary Protection Certificate (SPC) manufacturing waiver
- Advised the BIA board on Crown Use licensing

Connect:

- Engage and meet the needs of the wider BIA community by inviting speakers to share their company's IP interests & issues
- Host Summer and Christmas networking events

Inform/Support:

- Monitor and respond to developments in the Government's Brexit and trade policy and help shape the BIA's input
- Represent the sector in the courts where appropriate
- Monitor the implementation of the Unified Patent Court (UPC)
- Contribute to Nagoya activity in conjunction with EBAC and CGTAC

Expert advice:

- Provide advice to BIA members on relevant Supreme Court decisions to help them to take appropriate measures in response

Chair:

Stephen Ward, Cell and Gene Therapy Catapult

Vice-Chair:

Kit Erlebach, Fujifilm Diosynth Biotechnologies

BIA Secretariat:

Netty England

Connect:

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

Inform/Support:

- Delivered another successful programme for the 2019 bioProcessUK conference – 300 delegates and 43 exhibitors
- Contributed to the 2019 UK Bioscience Forum – Future Skills for UK Bioindustry panel session

Expert advice:

- Key pan-industry stakeholder within Life Sciences Industrial Strategy:
 - Worked with existing Industrial Strategy Challenge Fund investments and influenced future investments, aligning with the MMIP T&I workstream
 - Championed life sciences support through representation on the ISCF Medicines Manufacturing steering board
 - Major role in anchoring manufacturing of ATMPs for early phase academic-led clinical trials in the UK – business case submitted to funders
 - Skills delivery through successful BIA MAC LeaP initiative (44 on programme, 23 in 2018) and supported ISCF funded ATAC programme led by CGT Catapult (65 apprentices, 17 in 2018)
 - Input to Brexit consultations
- Represented BIA at the MHRA GMP/GDP consultative committee meetings

MAC

2020 priorities



Connect:

- 33 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 2020 bioProcessUK conference
- Contribute to the 2020 UK Bioscience Forum
- Aid in setting out a national skills provision for biomanufacturing for global impact:
 - Expansion of the very successful ISCF funded ATAC programme led by CGT Catapult
 - Leadership skills delivery through the popular BIA MAC Leap initiative

Expert advice:

- Key pan-industry stakeholder within Life Sciences Industrial Strategy:
 - Several MAC members represent the voice of the biologics/cell and gene therapy sector on the MMIP Leadership Team, seeking wider MAC contribution when appropriate
 - Set next generation analytics and associated data strategic vision for industry
 - Ongoing role in anchoring ATMP manufacturing for early phase academic-led clinical trials in the UK
- Represent BIA at the MHRA GMP/GDP consultative committee meetings
- Input into Brexit consultations and identify regulatory advantages where possible

Regulatory Affairs Advisory Committee (RAAC)



Chair:

Emma Du Four, AbbVie

Vice-Chair:

Andrew Fox, PsiOxus Therapeutics

BIA Secretariat:

Dr Christiane Abouzeid

Connect:

- Positive dialogue continued with MHRA and NICE – guests at RAAC meetings and speakers at BIA Regulatory Innovation Conference
- Significant engagement with MHRA to influence Brexit planning including no-deal contingency legislation and guidance
- BIA continued to lead EuropaBio regulatory policy group ensuring a strong link with RAAC, and established communication with BIO international regulatory team

Inform/Support:

- Successful BIA Regulatory Innovation Conference delivered with good engagement from stakeholders across the life sciences sector

Expert advice:

- Provided input into BIA policy work on medicines regulation post-Brexit and shaping MHRA planning

RAAC

2020 priorities



Connect:

- Act as a platform to bring together regulatory affairs representatives from the BIA community and use RAAC as a forum for engagement with UK regulators and key stakeholders, including the MHRA centres and NICE
- Maintain and build on existing BIA relationships with other regulators and trade associations, including ABPI, EuropaBio and BIO, on key regulatory topics of interest to members

Inform/Support:

- Support preparation and delivery of the 2020 BIA Regulatory Conference

Expert advice:

- Support BIA policy and engagement with UK Government in shaping 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

- Continued engagement with CSO and CMO communities
- Hosted Christmas networking event

Inform/Support:

- Designed and delivered the ‘Working Together to Shape the Future Workshop’ in Spring 2019 bringing SMEs and funders together
- Designed and delivered the ‘Bench to Bedside’ Webinar series : Preclinical considerations for clinical development culminating in a session on Advanced Therapies at the UK Bioscience Forum, October 2019
- Designed and delivered a ‘Manufacturing Science’ session for the 16th bioProcessUK Conference, November 2019

Expert advice:

- Active engagement with UKRI, other funders and MMIP
- Supported the BIA’s Spending Review activities, including principles for grant funding

SIAC

2020 priorities



Connect

- Continue engagement with CSO & CMO communities and with UKRI and other funders
- Christmas networking event

Expert advice:

- Influence relevant areas of science policy as Life Sciences Industrial Strategy and Sector Deals emerge, e.g. long-term funding environment and clinical trials
- Support the BIA's Comprehensive Spending Review activities, including position on potential new post-Brexit funding ecosystem
- Engage with UKRI and champion life sciences support post 2019 election and Brexit

Inform/Support:

- Support the formulation and delivery of 'Big Idea' proposal to establish the UK as a global leader in the Manufacturing, Digital and Analytical sciences for advanced biological products (ATMPs, advanced biologics and vaccines), aligning with other complementary funding proposals
- Design and deliver a Workshop - 'How can biotech SMEs best benefit from the revolution in the digital sciences?'