

February 2018

BIA Advisory Committees

Review of 2017 activity and 2018 priorities



Cell and Gene Therapy Advisory Committee (CGTAC)



Chair:

Sven Kili, GSK

Presenting today:

Emily Culme-Seymour, GSK

BIA Secretariat:

Rachael Mann

Cell and Gene Therapy Advisory Committee (CGTAC) 2017 review

- **Accelerated Access Review (AAR) and the NICE Advanced Therapy Medicinal Product (ATMP) mock appraisal** - Government response published in early November.
- **ATMP Manufacturing Task Force report** - CGTAC has been assigned actions relating to access and regulation and will support MAC with the skills recommendations.
- **Regenerative medicine** – House of Commons report published and the Government have responded.
- **Genome editing** – Informed BIA's written evidence for the House of Commons inquiry on Genomics and Genome-editing.
- **Micro-factories** – Developed project proposal for a pre-competitive community.
- **Promote the UK cell and gene therapy environment** – Held panel session at the BIA 2017 UK Bioscience Forum.
- **Explore opportunities with Japan** – Hosted guest speaker from CJ Partners to explain the Japanese regulatory landscape for ATMPs.

Cell and Gene Therapy Advisory Committee (CGTAC) 2018 outline

Connect:

- Contribute to BIA events as appropriate – e.g. UK Bioscience Forum.
- Contribute to international Cell and Gene Therapy events/engagement.

Inform/Support:

Inform BIA policy work/engagement on:

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

Expert advice:

- Develop a plan for contributing to the access and regulatory actions in the Advanced Therapy Manufacturing Taskforce Action Plan, in collaboration with MAC and RAAC.

Engineering Biology Advisory Committee (EBAC)



Chair:

Tim Fell, Synthace

BIA Secretariat:

Eric Johnsson

Engineering Biology Advisory Committee (EBAC) 2017 review

- **Communication:** EBAC members were in strong attendance at SynBioBeta London. EBAC also had representatives at other conferences, such as SynBioBeta San Francisco. EBAC has also promoted the UK engineering biology sector externally, particularly in relation to iGEM's potential move to the UK.
- **Advocacy:** EBAC discussed and provided input into the Life Sciences Industrial Strategy, BIA meetings with key stakeholders, and BIA's work on the Nagoya Protocol, in particular on the submission on Digital Sequence Information (DSI).
- **Increase investor awareness of and engagement with UK engineering biology:** The investor breakfast organised by SynbiCITE to coincide with SynBioBeta London was well attended by both EBAC members and a range of investors from the UK and overseas, which resulted in funding for several UK synbio companies. EBAC members were also involved in the BIA CEO and Investor Forum.

Engineering Biology Advisory Committee (EBAC) 2018 outline



Connect:

- Bring the UK engineering biology sector together and continue to showcase its strengths, within BIA membership and externally, including through BIA events, EBAC engagement at SynBioBeta, iGEM and other conferences.
- Attract new committee members by promoting the breadth and relevance of the sector.

Inform/Support:

- Input into relevant policy and public affairs activities via the BIA, including engagement on the implementation of the Life Sciences Industrial Strategy, other relevant Industrial Strategies, the Industrial Strategy Challenge Fund, and BIA Nagoya Cross-Committee Working Group.

Expert advice:

- Increase investor awareness of and engagement with UK engineering biology, e.g. at meetings around BIA's CEO and Investor Forum, conferences about the Fourth Industrial Revolution, and similar events.

Finance and Tax Advisory Committee (FTAC)



Chair:

Colin Hailey, Confluence Tax

BIA Secretariat:

Dr Martin Turner

Finance and Tax Advisory Committee (FTAC) 2017 review



- **Brexit and Industrial Strategy:** participated in BIA and Government-industry workshops and provided advice to the BIA.
- **R&D Tax credits:** fed into HMT review of R&D Tax Credit regime and represented sector on HMRC R&D Consultative Committee.
- **Venture Capital Schemes:** engagement with HMRC resulted in improved Advanced Assurance process and FTAC provided input to BIA response to Patient Capital Review securing improvements to EIS (Enterprise Investment Scheme) and Venture Capital Trust (VCT) schemes.
- **Consultations:** inputted to 7 BIA consultation responses, including Budget and Autumn Statement submissions and Financial Conduct Authority review of primary markets. Met with Office for Tax Simplification.
- **Patent Box:** produced BIA member guide.
- **Membership:** recruited new members to the Committee.
- **Wider outreach:** have supported BIA's engagement with the City.

Finance and Tax Advisory Committee (FTAC) 2018 outline



Connect:

- Continue to engage with non-members inside and outside the sector including the finance and investment community, invite a guest speaker to each meeting, and host inaugural Committee Drinks.

Inform/Support:

- Continue to generate ideas and support the BIA in relevant consultations from government and other bodies, including HM Treasury & HMRC.
- Implementation of relevant sections of Patient Capital Review will be a key focus. FTAC stand ready to support BIA engagement on implementation of changes to EIS, VCT and Entrepreneurs Relief.

Expert advice:

- Keep BIA members informed about developments, best practice and their responsibilities, as well as actively seeking member feedback and engagement, and represent the sector at government meetings and forums.

Intellectual Property Advisory Committee (IPAC)



Chair:

John Murphy, Vectura

Vice-Chair, presenting today:

Nicole Jadeja, Fieldfisher

BIA Secretariat:

Dr Martin Turner

Intellectual Property Advisory Committee (IPAC) 2017 review



- **Brexit:** Advised the BIA on IP issues and participated in IPO-MHRA-industry workshops.
- **Unitary Patent and Unified Patent Court:** Tracked implementation of the UPC, met with IPO officials, and produced a BIA member briefing.
- **US case law and patentable subject matter:** Hosted seminar with Konstanin Linnik. Successfully influenced EPO guidelines on patentability of products of essentially biological processes.
- **Nagoya Protocol and Access and Benefit Sharing:** Represented BIA members as guidance was developed and ensured BIA members are aware of how they might be impacted. Met with DEFRA officials on Parliament Day.
- Responded to two EU consultations on **SPCs** and submitted views to the IPO on **three referrals to the CJEU.**
- **Supported the BIA in a Supreme Court case intervention:** Warner-Lambert vs Actavis.
- Delivered **IP Hot Topics** session at the BIA UK Bioscience Forum.
- Hosted **summer drinks** and **Christmas lunch.**

Intellectual Property Advisory Committee (IPAC) 2018 outline



Connect:

- Host Summer Drinks and Christmas Lunch.
- Keep membership under review to ensure equitable representation of BIA community.

Inform/Support:

- Support the BIA in relevant consultations and Brexit activity, including forming an IP Brexit Working Group, monitoring implementation of the UPC, and contributing to the BIA Nagoya Cross-Committee Working Group.
- Contribute to content at BIA events as appropriate (primarily the BIA UK Bioscience Forum).

Expert advice:

- Provide advice to the IPO on CJEU case referrals, ensure BIA members are kept informed through briefings about developments in IP law and policy, and 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

BIA Secretariat:

Netty England

Manufacturing Advisory Committee (MAC) 2017 review



- Key functional delivery role within **Medicines Manufacturing Industry Partnership (MMIP)**:
 - Major role in delivering asks from the **Advanced Therapy Manufacturing Taskforce Action Plan**;
 - **Regulatory workstream** - delivered and kept live an evolving regulatory flexibility paper;
 - **Technology & Innovation workstream** – supported and encouraged biologics initiatives that came out of HVM roadmap refresh.
- Delivered another successful programme for the 2017 **bioProcessUK conference**.
- Delivered a session at the 2017 **UK Bioscience Forum** in partnership with CGTAC.
- Delivered next generation of **bioproduction leadership** programme.
- Represented BIA at the **MHRA** GMP/GDP consultative committee meetings.
- **Held** committee summer drinks and continued engagement with KTN.

Manufacturing Advisory Committee (MAC) 2018 outline



Connect:

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

Inform/Support:

- Deliver another successful programme for the 2018 bioProcessUK conference.
- Contribute to the 2018 UK Bioscience Forum.

Expert advice:

- Key pan-industry stakeholder within Life Sciences Industrial Strategy:
 - Propose 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; support delivery of standards and access actions with CGTAC and RAAC.
- Based on the great success of cohort 1, initiate cohort 2 of next generation of bioproduction leadership programme.
- Represent BIA at the MHRA GMP/GDP consultative committee meetings.

Regulatory Affairs Advisory Committee (RAAC)



Chair:

Alan Morrison, MSD

Vice-Chair:

Emma Du Four, Abbvie

Presenting today:

Chris Walker, Amgen

BIA Secretariat:

Dr Christiane Abouzeid

Regulatory Affairs Advisory Committee (RAAC) 2017 review

▪ **Brexit:**

- Provided regulatory support to help shape BIA's input and influence Government negotiating position on medicines regulation.
- Partnered with MHRA to assess practical regulatory implications and consider options/scenarios for post-Brexit regulatory framework.

▪ **Continued positive engagement with MHRA and NICE:**

- MHRA and NICE guest speakers attended RAAC meetings.
- Members formed delegation to bilateral BIA/MHRA meeting and engaged with MHRA/NICE on regulatory policy and market access.
- Supported BIA/MHRA conference 'Innovation in life sciences in a changing and dynamic environment', attended by 220 delegates across the life sciences sector.

▪ **New members:** Gilead, PsiOxus Therapeutics.

Regulatory Affairs Advisory Committee (RAAC) 2018 outline



Connect:

- Bring together regulatory affairs representatives from the BIA community and use this group as a key touchpoint for engagement with key stakeholders at a UK and EU level, including MHRA, NIBSC (National Institute for Biological Standards and Control), CPRD (Clinical Practice Research Datalink), NICE and the EMA.

Inform/Support:

- Support delivery of the joint BIA/MHRA 2018 Regulatory Conference.
- Input to BIA Brexit work, including input to help shape the post-Brexit UK regulatory framework and MHRA future role as part of the UK innovation ecosystem and at a global level; and minimising disruption to patient access to medicines after the UK leaves the EU.
- Support BIA work to improve early access to innovative medicines in the UK, including input to help shape the new accelerated access pathway for breakthrough products and engagement with NICE on relevant issues, for example information sharing to support NICE reviews, in line with AAR implementation.
- Strengthen collaboration with NIBSC, e.g. scientific dialogue on innovative products and technology platforms, including advanced therapies and linking across to work of both CGTAC and MAC in taking forward regulatory actions from the Advanced Therapy Manufacturing Taskforce Action Plan.

Expert advice:

- In addition to supporting work on key themes listed above, provide expert advice as appropriate, including providing BIA unique insights for a supportive regulatory environment for R&D and innovation, maintaining UK alignment with EU and international standards.

Science and Innovation Advisory Committee (SIAC)



Chair:

Mark Carver

Vice-Chair:

Penny Ward, Karus

BIA Secretariat:

Netty England

Science and Innovation Advisory Committee (SIAC) 2017 review



- Defined **SIAC's distinct role** and purpose within BIA ensuring engagement with priority stakeholders.
- Built active relationships with funders (e.g. UKRI, BBSRC, EPSRC, MRC), having various meetings through year.
- Ensured **SIAC was effectively marketed** to the CSO/CMO BIA community to increase awareness and improve engagement.
- Developed and ran **two events** focused on the scientific community
 - Making the UK a destination for translational research and early phase trials – afternoon seminar in March 2017;
 - Led on two sessions at the 2017 UK Bioscience Forum – on clinical trials and UK as a science hub.
- Delivered thought leadership on **Tech Transfer** – held lunch with members to develop BIA position on issue, shared with key stakeholders and Parliamentary Select Committees.
- **Represented the BIA** at scientific events as required by the BIA Senior Management team.
- Delivered BIA's science & innovation **webinar series** in 2017.

Science and Innovation Advisory Committee (SIAC) 2018 outline



Connect:

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

Inform/Support:

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

Expert advice:

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

Genomics Advisory Committee (GAC)



Chair:

Adrian Ibrahim, Wellcome Trust
Sanger Institute

Vice-Chair:

Anthony Finbow, Eagle Genomics

BIA Secretariat:

Rachael Mann

Genomics Advisory Committee (GAC) 2018 outline



Connect:

- Contribute to BIA events, including BIA activity at JP Morgan and a panel session at the 2018 UK Bioscience Forum.
- Engage with Genomics England to inform their business model.
- Keep a watching brief on international developments in genomics.

Inform/Support:

Inform BIA policy work on:

- Implementation of the Life Sciences Industrial Strategy and the Sector Deal, specifically HARP (Health Advanced Research Programme);
- Data issues - implementation of the GDPR and the establishment of five national data hubs;
- Genomic medicine in the NHS – support SME representation on the National Genomics Board.

Expert advice:

- Produce an explainer of the UK genomics industry.