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|  | Industry Involvement in the Advanced Therapy Treatment Programme (Case Study for ATTC Website) | | | | |
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A collaborative approach to best practice in ATMPs: The ATTC Industry Advisory Group

The challenge

Over the past decade, we have seen remarkable growth in advanced therapy medicinal product (ATMP) development, clinical trials, and licensed products. The area of advanced therapies is relatively new; however, advances in technology have driven this industry to grow at a significant rate. The Advanced Therapy Treatment Centre (ATTC) programme spans academia, the NHS and industry and utilises this close partnership to enable these innovative treatments to be more efficiently and effectively delivered to patients. The companies involved with developing ATMPs face a myriad of challenges in supply chain, manufacturing, tracking, and tracing of materials from and to hospitals, governance, clinical trials and adoption. Currently, the expertise within the ATMP ecosystem is variable. Industry is at different stages of development, trailing or marketing of their products interacting with healthcare systems that have similar variability in their expertise and ability to utilise these products. Each participant in the industry needs to work together, share knowledge, and have opportunities to network to develop standardised approaches and best practices for the field.

The solution

The ATTC Industry Advisory Group (IAG), facilitated by Cell and Gene Therapy Catapult, brings together ATMP manufacturers operating in the UK, from small biotech to multinational pharmaceutical companies. The forum provides a safe place for industry to meet, discuss issues and work towards common solutions. The group also counts representatives from NHS England and the MHRA amongst its membership, providing a space for companies to have discussions with the NHS on the clinical and regulatory requirements for the adoption of ATMPs. The IAG has been a huge success from the ATTC programme, now having 79 partners involved and actively engaged in a positive manner to support and develop this industry in the UK.

The IAG has supported delivering on the Accelerated Access Collaborative (AAC) work streams, crowd sourcing solutions to barriers and accelerating the introduction of ground-breaking new treatments.

The IAG work streams have produced a wide-ranging output delivered through the expertise within the working groups across logistics, starting material procurement & labelling, trial costing and contracting as well as public consultations on processes affecting ATMPs. Some examples of outputs delivered in this way are:

Aide Memoire to Procurement Site Readiness: *A product of collaborative working is the development of an Aide Memoire to Procurement Site Readiness. The document tackles the audit fatigue experienced at NHS sites across the UK and captures all site, regulatory and the most common industry evidence of practice requirements. The document can be found here:*

<https://www.theattcnetwork.co.uk/wp-content/uploads/2022/07/Aide-Memoire-Procurement-Site-Qualification.pdf>

Poster Presentation – Non-label data capture: *A poster presentation demonstrating the data transferred between NHS procurement sites and ATMP manufacturers in an exemplar apheresis procedure. The collaboration between the IAG Procurement & Labelling Working Group was vital for the generation of this poster with particular thanks to Autolus, Gilead and Novartis. The Poster can be found here:*

<https://www.theattcnetwork.co.uk/wp-content/uploads/2022/02/Poster-Presentation-%E2%80%93-Non-label-data-capture-through-an-exemplar-apheresis-process.pdf>

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ATiMP Clinical Trial QTA Guidance: *The development of guidance to support the set up and implementation of ATiMP clinical trials quality technical agreements within the NHS sites. A link to the guidance can be found here: <https://www.theattcnetwork.co.uk/wp-content/uploads/2022/02/ATiMP-Clinical-Trials-Quality-Technical-Agreement-Guidance.pdf>*

Having the NHS partners involved in the IAG has resulted in a two-way dialogue that benefits both industry and the NHS. Industry now has a deeper understanding of the requirements for the adoption of ATMPs by the NHS. The NHS has an excellent view of what products are in development and can establish a dialogue with potential vendors in a neutral environment. Some products of this collaborative approach are:

Model Clinical Trials Agreement: *An excellent demonstration of the partnership between industry and NHS is in the generation of a ATiMP relevant model clinical trials agreement for use in the NHS. The agreement was produced leveraging the knowledge and experience of both industry and the NHS for the betterment of both. A link to the ATiMP model clinical trials agreement can be found here https://www.theattcnetwork.co.uk/wp-content/uploads/2022/07/CRO-mCTA_ATiMP_Jun_2021.docx and the associated guidance here: <https://www.theattcnetwork.co.uk/wp-content/uploads/2022/07/ATiMP-mCTA-CRO-mCTA-Guidance.docx>*

Through the IAG we have also run a closed workshop with regulatory agencies and other specialists to help develop plans for approval, reimbursement, and marketing.

ATMP Ecosystem Roundtable: *An example of which being the Industry and Cell and Gene Therapy Catapult sponsored roundtable discussion 1st November 2021, at which past, present, and future challenges in the ATMP ecosystem were discussed by subject matter experts. A report on the event can be found here: <https://www.theattcnetwork.co.uk/wp-content/uploads/2022/03/FINAL.-ATTC-Roundtable-slides.pdf>*

National Cell and Gene Therapy Vision for the UK: The event raised the need for a UK wide strategy for cell and gene therapies, and delegates agreed for the results of the discussions to be formed in a vision document outline what such a strategy would need to look like. The Cell and Gene Therapy Vision can be found here: <https://www.theattcnetwork.co.uk/wp-content/uploads/2022/03/National-Cell-and-Gene-Therapy-Vision-for-the-UK.pdf>

Making further impact

The IAG has already brought benefits to both industry and the NHS by allowing direct and open communication both ways. The next wave of benefits to both parties will be continuation of the development of standardised approaches to tissue & cell procurement, manufacturing, labelling and supply chain in the UK and beyond.