

TrakCel launches Consultancy Services to share extensive cell and gene therapy process development expertise

- **TrakCel Consultancy Services will leverage company's experience to help early-stage developers reduce inefficiencies and enable flexible growth**
- **Expertise based on 12 years of helping develop and manage processes for more than 15 therapy classes, and supporting four commercial therapies**

Cardiff, UK, January 16, 2024 – TrakCel, the leading and proven provider of cellular orchestration systems to the global cell and gene therapy (CGT) industry, today launched TrakCel Consultancy Services to efficiently share its extensive process development experience with the broader community of CGT developers. The new consultancy services will be dedicated to helping therapy developers progress through the complex clinical environment, with consultancy services including Chain of Identity Strategy & Methodology, Data Protection Compliance, Label Design & Compliance, Supply Chain Risk Assessment and SaaS within CGT/Pharma.

TrakCel Consultancy Services will be managed by Matthew Lakelin, Ph.D., a co-founder of TrakCel who brings a wealth of experience in client processes and supply chain, product and roadmap development, regulatory landscape and more. In his role as Head of Consultancy Services, Lakelin will manage a team of consultants and subject matter experts who have likewise supported TrakCel's extensive list of CGT clients through their clinical journeys, including four that cleared marketing approval.

Through the rapid increase in CGT developers entering clinical trials, an understanding has crystallized around the need to start programs from a sustainable and cost-effective position. This includes a new emphasis on managing regulatory and supply chain considerations, allowing a greater share of resources to remain dedicated to development. Therapy developers who have long turned to TrakCel to help manage their clinical and commercial journey recognize the value of its partnership, leveraging the company's experience and expansive network of collaborators across the entire value chain. TrakCel supports over 25 CGTs at every step of clinical development and has seen many of them progress through multiple stages to commercialization.

"The launch of TrakCel Consultancy Services reflects extensive feedback from throughout the cell and gene therapy industry. At early stages, when resources are tight and developers are still forming both teams and processes, it is essential but challenging to find reliable collaborators that can help deliver these therapies safely," said Lakelin. "It is increasingly necessary for companies to strategically build digital solutions and plans for scale-out and commercialization into the earliest stages of development. Whether at set-up, clinical inflection points or anywhere between, TrakCel is uniquely positioned to tap into the collective experience and deliver, based on our work over the last decade."

Orchestrating CGTs over the full clinical trial process often involves changing and adapting processes at pivotal points such as scale-out or territorial expansion. Issues like label design that seem as though they should be simple can yield unexpected regulatory and technical complexity, where an unconsidered layout, translation or element create delay and issues late in the process. In a highly regulated industry, any change needs to be managed closely, but doing the groundwork to set up systems and processes at early stages can simplify how change is implemented. TrakCel has seen several clients suffer the same pitfalls, and with TrakCel Consultancy Services, can help others avoid unnecessary complexity and inefficiencies.

About TrakCel

TrakCel is the market leading developer of integrated cell orchestration solutions and services. TrakCel has specifically designed these solutions to manage the international autologous and allogeneic cell, gene and immunotherapy value and supply chains. Its orchestration platform has evolved in collaboration with, and is increasingly adopted by, leading companies in the cell, gene and immunotherapy industries. The service portfolio includes training, support and consultancy offerings, all tailored to the unique needs of the CGT sector and drawing on TrakCel's extensive experience in the industry.

TrakCel's SaaS solutions enable real-time control for all organizations working across the entire therapeutic value chain. This control includes patient eligibility (commercial) and enrolment, sample collection, manufacturing and treatment delivery. TrakCel aims to enable accelerated global scale-up and scale-out of cell and gene therapy products, increasing efficiency and decreasing complexity, while safeguarding Chain of Custody (CoC), Chain of Identity (CoI) and audit trail for efficiency, compliance and traceability. Founded in 2012, TrakCel is headquartered in Cardiff, UK with offices in the US. For more information, visit www.trakcel.com.