VISICORT - A CASE STUDY IN CELL THERAPY TRANSPORTS

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Peadar Mac Gabhann graduated from the National University of Ireland, Dublin with a M.Sc. in Industrial Microbiology. He carried out post graduate research at the Netherlands Cancer Institute (NKI) Amsterdam, Biogen at ETH Zurich and the Faculty of Medicine at Kyoto University Japan. He joined Schering Plough Corporation as a key member of staff in the start-up of the first, world-wide Biopharma facility in Cork to produce Interferon in 1983. As Director/ board member of Schering Plough Japan, he led the company's research and Asian business development. Peadar has >30 years' experience in the international pharmaceutical industry. In the past 10 years, he co-founded and directed two Life Science start-ups and participated in several international EU FP7 projects: He is a regular presenter at international events & presented a position paper on "Biobanks - Key Resources for Advancement of Biotechnology & Human Health" to the expert group of the EU Parliament on the Future of Medicine.

Currently he consults with Jacobs Engineering on the design/construction of major Biopharma facilities throughout Europe, he lectures in Pharmaceutical Business at Griffith College Dublin as well as running a certified Tissue Establishment in Wexford, Biostór Ireland.

VISICORT

Each transport of cell therapy products requires in-depth, case-by-case analysis & validation. This is very difficult to anticipate and plan in our rapidly changing world.

Corneal disease is a leading cause of blindness worldwide & affects all genders & age groups. There are >100,000 corneal transplants performed annually. Unfortunately, 20-30% of transplants fail within five years & 40-60% within ten years. VISICORT is an EU FP7 project researching ways to improve the success rate of Corneal Transplantation. Biostór Ireland, a lead partner in the consortium, was tasked with biospecimen management and transport. To date we have performed >195 VISICORT cold-chain transports from clinical trial sites in Germany, Denmark, France, UK and Ireland. In addition, we have created a Foundation biobank of >50,000 biospecimens for future research in eye diseases.

VISICORT is developing a cell therapy to activate the immune system in order to reduce the risk of acute rejection of corneal re-transplants. The clinical trial will establish the safety and tolerability of two IV infusions of allogeneic human bone marrow-derived mesenchymal stromal cells (BM-MSC) and evaluate the potential efficacy of pre-transplant intravenous infusions of allogenic-BM-MSC on high-risk corneal transplantation patients. Seven cell therapy transports are planned between the Centre for Cell Manufacturing Ireland (CCMI) in Galway and the clinical trial site in Charite Hospital, Berlin.

As with all EU-funded projects, estimated budget requirements were submitted with the project proposal in 2012. Six years later the reality is very different as are the transport costs. One major issue that has significantly impacted road transport of human cell products for human application is the current European Refugee Crisis which started in 2015 when increasing numbers of people began arriving in the European Union (EU), from across the Mediterranean Sea and overland through Southeast Europe. To stem illegal immigration routine X-Ray of trucks was introduced at ports.

An LN2 Cryoshipper can be efficiently transported from Biostór Ireland in Rosslare to the Charite Hospital in Berlin, Germany across the UK land bridge in 3 days, well within the 12-day validated window and at a relatively low cost of €400. However, since the advent of the Refugee Crisis, all trucks travelling between the UK port of Dover and the French port of Calais are now subject to X-ray. As you can appreciate, it is nearly impossible to coordinate a transport of cells between the UK and French customs from the island of Ireland, add to that the likeliness that the driver is not fluent in either language and may not understand the special requirements of the cargo s/he is transporting. So, in the future, road transport of human cells for human applications from Ireland to EU countries can no longer be considered. The alternative, air shipment is highly efficient with next day delivery. However, it includes more third-party handling and is 4-5 times more expensive. To avoid X-ray transport scans, Biostór was required to become a "Known Consigner" with the Irish Aviation Authority (IAA) – a detailed systematic process involving: police vetting, extensive training and training validation in airline security, followed by a comprehensive, on-site audit of security procedures with associated costs that were not included in the VISICORT budget.

What's next to impact cell transports from Ireland? With the Brexit deadline looming, one wonders what customs issues will impact the ports between Ireland, the UK, and the EU to further complicate the transportation of products in our fledgling Cell Therapy logistics business. It is estimated that borders will require 10 times more customs staff than they currently have in order to process the endless paperwork needed to enter the EU from a Third Country: an export declaration, an ATA Carnet from customs officers, invoices for products they are hauling, insurance certificates and a transport permit for each EU country they will drive through etc. etc.

For a glimpse of what border trade between a Third Country and the EU could look like post-Brexit see Turkey's northern border with Bulgaria, one of the busiest crossings in Europe and a good example of how bad things can become. On a good day, a 5km line of trucks crawls along the highway towards the border. On a normal day, there is a 7-8km line of trucks. The record is 18km and it can take up to 30 hours to get through. For the highly-regulated life science industry, Brexit has the potential to become catastrophic resulting in added administrative requirements, uncertainty over duties, extra databases, additional security checks, listings and rules of origin procedures, and it doesn't appear that any country has started to put the infrastructure and the trained personnel in place to deal with this pending bureaucratic nightmare.

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