Accelerated product development through collaboration

The challenge:
Advanced therapy supply chains are significantly more complex than those of traditional pharmaceutical products; many have patient-specific components requiring a circular supply chain and chain of identity management throughout to ensure patients receive the correct drug product - the implications of this failing could be fatal. Thus, tracking these therapies from start to finish is essential for safe, compliant, and cost-effective delivery of treatments to patients. However, this tracking is complex as it involves consolidating and analysing detailed data from multiple partners and systems quickly enough to drive critical decisions. Additionally, supply chain steps for new therapies can vary significantly, such as an autologous vs allogeneic therapy, further complicating management. The speed required and the need to audit and report the data means that traditional, paper-based processes quickly become difficult to support and can contribute to delays, errors or missing information.

The solution:
Implementation of TrakCel's cellular orchestration software to manage the supply chain for both autologous and allogeneic advanced therapies will provide real-time information about the location, status, and condition of patient samples and therapies to key decision makers. This information assists in driving efficiency and informs critical decisions, helping to prevent delays and dangerous mistakes. Integration between TrakCel's solution and World Courier's logistics software automated data exchange and allowed real-time tracking and reporting of each therapy's journey from end to end. The solution ensured adherence to regulatory requirements and best practice, whilst documenting all activities electronically, removing the need for extensive paper-based records.

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The results:

TrakCel's platform was deployed within the Advanced Therapy Treatment Centres (ATTCs) for an allogeneic and autologous therapy. As well as simplifying the supply chain, reducing demands on staff time, and ensuring regulatory compliance, this offered insight into changes required to manage these diverse therapies.

Collaboration with key stakeholders at different points of the treatment process has shaped the TrakCel product. The Midlands and Wales ATTC and the Northern Alliance ATTC helped develop the solution in line with evolving customer and clinical requirements; integration work with World Courier offered automation and insight into supply chain partner requirements and input from University Hospital Birmingham's Cancer Clinical Trial Unit resulted in new features and functions, including dashboards, reporting and enhanced patient identifier management.

The solution also yields cost advantages, reducing administrative time spent scheduling manufacture and co-ordinating deliveries, minimising costs due to errors and wasted product and simplifying the generation of an audit trail. This demonstrates how other developers can similarly reduce costs.

Wider impact

Improvements identified in the ATTC project by working alongside Orbsen Therapeutics were pivotal for the newest iterations of TrakCel's solution. ATTC-related software modifications have led to enhanced support of allogeneic therapies, which has been invaluable for TrakCel as the pipeline of allogeneic therapies is growing. Working with stakeholders across the whole supply chain highlighted where modifications could help address the challenges faced at specific points of an ATMP's journey. This has resulted in an evolved platform, designed to facilitate integration with supplier applications and improve use of shared data. In addition, TrakCel's platform can now manage multiple treatments with different supply chain needs from one system, and scale as needed for global trials or commercial products. This should ultimately assist researchers and healthcare providers in offering patients a wider range of treatment options including advanced therapies, more cost-effectively moving forward.

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