Empowering the NHS advanced therapies ordering prototype IT system with Manufacturing insight from an electronic batch manufacturing system

A prototype software platform aims to increase efficiency in the production of advanced therapies – helping to drive down costs and increase supply of these cutting-edge medicines

Advanced Therapy Medicinal Products (ATMPs) – also known as gene or cell therapies – are at the cutting edge of personalised medicines. They are driving remarkable changes in clinical practice across multiple fields of medicine, including new cancer therapies, regenerative treatments, and enhanced wound healing. However, they are also very expensive, often costing hundreds of thousands of pounds to millions of pounds per treatment.

This is because many ATMPs are made from a patient's own cells. While this bespoke production creates a truly personalised medicine, it means the manufacture and supply of advanced therapies is uniquely challenging.

"Making ATMPs is very different from paracetamol or vaccines, for example. Each batch needs to be tested, approved and the manufacturing data captured, but whereas ordinary medicines can be made in batches of 100,000+ in one manufacturing run, each batch of ATMP only produces one treatment," explains Kwok Pang, COO of Autolomous, a company that designs software solutions for the ATMP supply chain. "It's a major challenge for both manufacturers and the NHS to deliver the process at scale."

With £500k funding from the Made Smarter Innovation challenge, Autolomous led a project with Advanced Therapies Facility, University of Birmingham and the University Hospitals Birmingham NHS Foundation Trust to integrate its software platform – AutoloMATE – to the NHS protype advanced therapy ordering system that streamlines the scheduling and ordering system for ATMPs.

Creating an advanced therapy requires a drug company to organise the collection of patient cells, transfer them to a manufacturing site, undergo a complex manufacturing process, and then precisely time the delivery of the therapy back to the hospital in time to treat the patient.

"Currently, the scheduling is largely managed and organised by individuals using diaries, white boards and emails being sent back and forth. In addition, they are dealing with a live cell product, which leads to unpredictability in the supply chain. And on top of all that, there is no margin of error in this type of manufacturing; the wrong product to a patient could kill them," says Pang. "To account for all these considerations, current schedules allow large buffers of time. It means the manufacturing teams cannot work at full production capability." By creating an interface between these systems, AutoloMATE aims to increase efficiency and maximise production capacity – enabling greater quantities of advanced therapies to be produced, and at a lower cost.

The project builds on and integrates existing technology developed by

the Advanced Therapies Treatment Centres initiative funded by UKRI. In this project, the integrated platforms demonstrated an 85% reduction in scheduling and 50% reduction in manufacturing time. "Importantly, because it removes so many of the manual elements, it also improves the overall safety profile of these complex medicines. This is key to demonstrating to regulators that scaling up can be achieved with no increase in risk," adds Pang.

Moving forward, Autolomous is working to demonstrate the platform could be rolled out across NHS centres of excellence. "This is a fast-growing sector, with more 2,000 clinical trials in progress for personalised medicines – and some of these are for treating diseases with much larger patient populations," says Pang. "Digitisation frees up production capacity and optimises the skills of those working in the industry. Increased efficiency along the value chain can drive down costs and help create a better understanding of the product, all of which will help cure more patients in future."

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