

COST-EFFECTIVE MANUFACTURING STRATEGIES FOR FEASIBLE COMMERCIALISATION OF AUTOLOGOUS CAR T-CELL PRODUCTS

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Chimeric antigen receptor T-cells (CAR T-cells) have been proposed as a possible treatment for multiple oncology indications, showing significantly high response rates in patients which have failed to respond to previous treatments. The manufacturing process of these promising products poses challenges inherent to autologous therapies. These challenges include: high COG, high labour and high facility footprint requirement. This presentation describes a detailed economic analysis of the commercial scale manufacture of multiple CAR T-cell products. This analysis was carried out using an advanced decisional tool developed at University College London. The case study assesses the cost effectiveness of multiple combinations of technologies for whole process manufacture of CAR T-cell products, using different viral vectors under multiple dose size and demand scenarios. The key cost drivers across these scenarios were identified through a detailed sensitivity analysis. This allowed process performance targets for feasible commercialisation of CAR T-cell products to be set, under different reimbursement plans. The case study was also extended to explore the potential cost benefits of shortening the cell culture process through process optimisation. Multiple process schedules were explored in order to reduce resource requirement and facility footprint, and a detailed NPV analysis was carried out with the aim of capturing the potential economic and technical benefits of using different manufacturing strategies over several years including: manufacturing technologies, process schedules, viral vectors and facility configurations (centralised manufacture vs decentralised manufacture vs hospital site manufacture).