

A ROADMAP TO SUCCESSFUL COMMERCIALISATION OF AUTOLOGOUS CAR T-cell PRODUCTS WITH CENTRALISED AND BEDSIDE MANUFACTURE

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Key Words: Cost of goods (COG), net present value, process economics, supply chain, reimbursement, centralised, decentralised, bedside, GMP-in-a-box, market access

The availability of two CAR T-cell therapies on the market has cemented the therapeutic potential of these products to treat oncology patients. However, in order for CAR T-cell therapies to be available to a wide number of patients, cell therapy developers must carefully design their manufacturing and commercialisation strategy. This analysis must take into account multiple factors related to the target market characteristics (EU v USA), the product features (e.g. dose size), manufacturing process (e.g. automated v manual platforms) as well as facility network (e.g. centralised v bedside manufacture) and supply chain requirements (e.g. fresh v frozen products). This presentation aims at assessing the implications of the choices made for each of these critical factors to provide a clear framework for decision-making during early stages of the development process of autologous CAR T-cell products. The resulting roadmap enables the successful commercialisation of these powerful therapeutics. This analysis was carried out using an advanced decisional tool developed at University College London. The case study assesses the economic and operational effects of the decisions made at the different levels of manufacturing and commercialisation strategy by computing metrics such as cost of goods, fixed capital investment, net present value, personnel requirement and facility footprint, while considering potential constraints relating to technology capacity, viral vector stock availability, product shelf life, market access and reimbursement strategies.