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CELL THERAPY MANUFACTURING STRATEGIES: IMPACT ON COST OF GOODS, COST OF DEVELOPMENT AND COMMERCIALISATION

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Successful commercialisation of cell therapies will be underpinned by cost-effective, robust and scalable manufacturing processes, practical supply chain solutions for delivery to patients and early planning of reimbursement. UCL's Decisional Tools team have developed advanced decision-support tools that effectively integrate concepts from bioprocess economics, risk analysis, and combinatorial optimization to address such challenges. This presentation will provide some of our most recent process economic insights from such models applied to current and future cell therapy manufacturing processes. Bottlenecks in upstream and downstream processes will be identified and the technical innovation required to bridge the gaps constraining commercialisation will be discussed. Parallels and key differences with the historical development of biopharmaceuticals will be highlighted. A discussion of the cost of goods in relation to reimbursement will be provided for different cell therapies and compared to biopharmaceuticals. A series of industrial case studies will be presented to highlight economic challenges for different allogeneic and autologous cell therapy products. The case studies will address questions such as: What are the most cost-effective process technologies to use for cell culture, differentiation and recovery for different allogeneic and autologous scenarios? What are the cost and risk implications of process changes to more scalable and cost-effective technologies at different stages of a cell therapy's lifecycle? How do the lower costs of commercial manufacture with microcarrier systems relative to planar technologies weigh up against the cost of development? What is the impact of centralised versus decentralised facility designs on the costs of manufacturing and logistics to reach the patients. The insights from such questions are critical to helping the cell therapy sector achieve the manufacturing and commercial success of biopharmaceuticals.