CAR T-CELL THERAPIES: THE CONCEPT OF A DYNAMIC SUPPLY CHAIN

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Novarti's Kymriah and Kite's Yescarta, are the first Chimeric Antigen Receptor (CAR) T-cell therapies to receive regulatory approval both in the United States and in Europe. They are suggested as new face in cancer treatment and in particular in B-cell acute lymphoblastic leukaemia (ALL). Their promising results have encouraged numerous research groups and manufacturers to explore the potential of those therapies in the treatment of various cancer types, resulting into 317 clinical trials globally (based on a recent search on ClinicalTrials.gov (2018)). Today, in the UK CAR T cells are only available through clinical trial schemes (approximately 250 patients per trial), thus being produced and delivered at a small scale. However, their recent European Medicines Agency Approval will allow them to become available to a wider patient population (approximately 40,000 eligible patients by 2031 (Figure 1), based on research performed on the UK patient population), requiring, therefore significant scale up/out both in the manufacturing line as well as in the logistics/supply chain model. In this work we focus on the design of a modelling tool to assist the decision making in the design of the supply chain model of CAR T cell therapies. Expanding our previous work (Wang et al., 2018), we demonstrate the design of a Resource Technology Network (RTN) for the identification of the key steps/decisions in the CAR T supply chain model. Based on previous qualitative results (Papathanasiou, 2018), we present a comparison between three supply chain model structures and we introduce the concept of the "dynamic" supply chain model. The latter refers to a versatile supply chain network that is tailored to the varying therapy demand. Based on the demand profiles, the modelling tool decides on: (a) number and location of clinical sites, (b) number and location of manufacturing sites and (c) best means of transport for the therapy. Lastly, the model considers time restrictions related to product shelf life, as well as different business decisions (e.g. in-house versus outsourcing quality control).

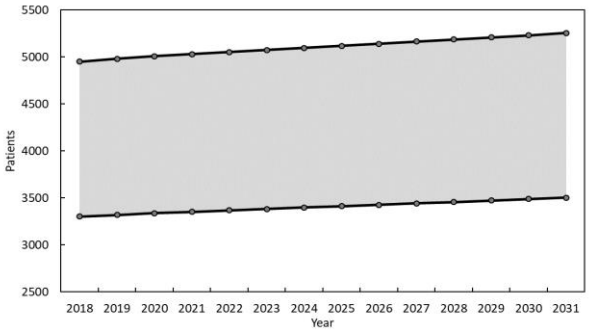

Figure 1 Forecast scenario of patient population eligible to receive CAR T cell therapies by 2031. Calculations are based on the assumption that only 10% of the patients with B-cell malignancies in the UK will be able to receive the therapy.

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