

CONFRONTING THE ANALYTICAL CHALLENGES OF CHIMERIC ANTIGEN RECEPTOR T CELL

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Intensive research and development effort has been devoted to Chimeric antigen receptor T (CAR-T) cell therapies. CAR-T presents unique challenges for analytical development due to its complex mechanism of actions, large heterogeneity of the starting material, the need for appropriate reference material, and the limited lot size and testing material. This presentation will use Lisocabtagene maraleucel as a case study to illustrate how an integrated analytical strategy enables the development of a late phase CAR-T program.