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NOVEL IMAGING STRATEGIES TO ASSESS HUMAN IN-VIVO CELLULAR DISTRIBUTION AND PERSISTENCE

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SUMMARY

It is inevitable that during the progression of clinical trials from early phase to later phases products and process will need to evolve. This poses significant risks as these products are complex and variable and comparability is difficult to control. Sponsors need to develop these products whilst avoid risks of repeating expensive clinical trials. The author will present strategies to support commercial development of a cell therapy product using data from an ongoing CAR-T study for cancer where a complex process had to be evolved into a new process as key materials and technology were no longer available and to accommodate new analytical strategies as well as to help an academic process become "investor ready". This means that not only should processes be closed, using appropriately commercial clinically approved materials, but also that the cost of goods are minimised. Ultimately this should result in reduced variability and avoid one of the most costly events in CAR-T cell manufacturing which are production failures. The ultimate objective is to establish a process that can continue evolving as it advances to standard of care commercial supply. The lessons of this strategy can be applied to any complex cell therapy.