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Cellular and gene therapy medicine management systems

PD Dr. Claudia Langebrake, University Medical Center Hamburg-Eppendorf

Abstract

Chimeric Antigen Receptor T cells (CAR-T cells) are a type of Advanced Therapy Medicinal Product (ATMP) classified as ex-vivo (cell-based) gene therapy. Since they are biological drugs, they are more complex than conventional drugs in terms of production and administration as well as regulatory and organizational aspects.

The Pharmacist Working Group of the European GoCART Coalition recently published recommendations for the implementation and operational management of CAR-T cell therapies, which will be presented and discussed. This involves considerations for hospital pharmacies in the implementation of a CAR-T cell service, as well as operational considerations in the patient and product pathway.

In addition, special features of clinical pharmacists' medication management in the context of an interprofessional team will be highlighted: for example particular aspects of the dosage of lymphodepletion with special regards to pharmacokinetics of fludarabine as well as the management of specific conditions, like cytopenias, cytokine release syndrome (CRS) and immune cell-associated neurotoxicity syndrome (ICANS).