

EMA has published a new report on CAR T-Cell therapy Registries

In February 2018 the European Medicines Agency (EMA) hosted a stakeholder workshop to evaluate the use of existing patient registries, and especially post-authorization follow up, for the benefit-risk evaluation of Chimeric Antigen Receptor (CAR) T-cell therapy. The workshop was part of the EMA's *Initiative for Patient Registries* which aims at agreement by stakeholders on implementable recommendations for the advance of evaluation and monitoring of CAR T-Cell therapies.

The report published in May 2018 summarizes these recommendations based on the findings of the workshop. Its participants, having clinical, regulatory or development experience with CAR T-Cell products, discussed topics of registry governance, patient consent, data sharing, data quality, registry interoperability and core common data elements needed. For actions aiming on facilitating and improving registry data use, a set of commonly-defined data elements can be found in Appendix 1.

First the data element definitions need to be harmonized across different registries, particularly those operated by the European Society for Blood and Marrow Transplantation (EBMT) and the Center for International Blood and Marrow Transplant Research seated in the United States. This way arrangements can be found to permit data sharing and an improved communication between registry holders, regulators and marketing authorization holders as well as applicants.

Besides recommendations the report also names barriers as well as actions for each stakeholder.

Initiative for patient registries:

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/10/WC500195576.pdf

Report - CAR-T cell therapy registries workshop

http://www.ema.europa.eu/docs/en_GB/document_library/Report/2018/05/WC500249247.pdf

Appendix 1:

Proposed data elements relating to efficacy and to safety - CAR-T cell therapy registries workshop

http://www.ema.europa.eu/docs/en_GB/document_library/Report/2018/05/WC500249248.pdf

Appendix 2: Agenda and Participants - CAR-T cell therapy registries workshop

http://www.ema.europa.eu/docs/en_GB/document_library/Agenda/2018/01/WC500242395.pdf