The supply chain of CAR T-cell therapies

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REFERENCES:

BACKGROUND

CAR T-cell therapy:

- First conceptualized at the end of 1980s [20]
- First approval: August 2017 (FDA – US) [23]
- Complete response rates between 69% and 90% in pediatric patients with relapsed or refractory acute lymphoblastic leukemia (ALL) in phase 1 trials [11]
- Completed and ongoing trials: around 95 [17]
- Costs: 475,000$ and 373,000$ (supply chain costs represent approximately 30%) [17, 9]

OBJECTIVE

To identify challenges and opportunities of CAR T cell therapy supply chain management.

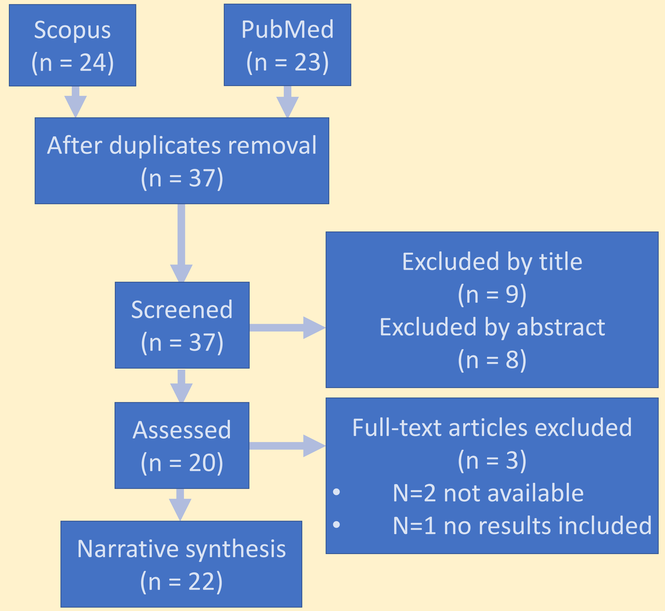
METHODS

Systematic literature review:

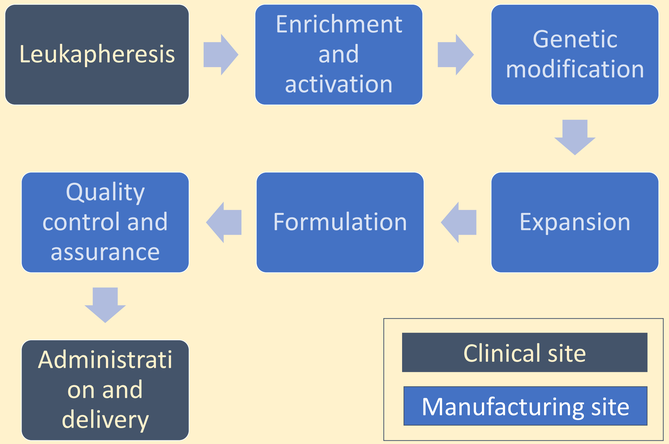
- CAR T cell therapy supply chain and logistics
- PubMed and Scopus (February 2021)
- Search string: TITLE-ABS-KEY (supply AND chain OR logistics AND car AND t)
- PRIMSA flow-chart

RESULTS

Systematic literature review - PRISMA flow chart:



CAR T-cell therapies process:



DISCUSSION / CONCLUSIONS

CAR T-cell therapies proved to be effective and increasingly efficient for the treatment of tumors, especially in pediatric patients.
Several challenges and opportunities related with CAR T cell therapies supply chain emerged from the literature review, as reported in the table below.
“Supply chain models will have to adapt to be fit for purpose” [17] and different models have been developed to allow these problems to be overcome.

		Challenge	Opportunity
Pre-market	**Research**	safety, efficacy and adverse events management / still in progress	innovations
	Information	availability and data processing capacity	big data
Manufacturing	**Technologies**	quality and personalization / customization, data safety	process optimization, integration, efficiency, agile processes, productivity
	Organizational models	centralization / decentralization; single facility / network	offshore production and turn-around
	Materials supply	allogeneic models	economies of scale
	Planning	flexibility	standardization and organized processes
Post-market	**Long-term safety**		
	Resources	availability and reimbursement	
	Logistics aspects	shipping and storage of living fresh / cryopreserved cells; cross-border shipping	
	Clinical adoption	professional integration and availability of trained physicians	effectiveness; holistic vision (Molecular Tumor Board)
	Collaboration of multiple stakeholders	coordination (patients, research, institutions, production plants, suppliers, hospitals, shipping)	cooperation (patients, research, institutions, production plants, suppliers, hospitals, shipping)