



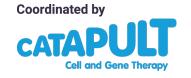


# CAR-T vein to vein process









### CAR-T vein to vein high level process flow



Adoptive cellular therapy using CD19 targeted chimeric antigen receptor (CAR) T cells has benefited from significant technological advancements and led to remarkable clinical outcomes in selected haematological malignancies. Major steps in chimeric antigen receptor-T-cell (CART) end to end process are Apheresis collection, cryopreservation of apheresis product, shipping of cryopreserved apheresis product, manufacturing of CART product (T-cell selection, T-activation, Gene transfer, T-Cell expansion, T-cell formulation, T-cell cryopreservation), delivery of Cryo product to the cell lab/hospital, thawing of CAR-T product, infusion of CAR-T product and patient follow up.

	CAR-T
Company Name	
Product Name	
Indication	
Eligibility	
Approval	
Treatment type	

Location	Responsibilities	
Hospital	Patient consultation, selection and consent at hospital; product order from Manufacturer, product receipt & verify by pharmacy and Thawing and infusion of the product and patient follow up.	
TAS	Collection of Starting Material(SM), Labelling and issue of SM for manufacturing of product.	
SCI	SM evaluation, cryopreservation, storage, issue the cryopreserved SM to Manufacturer, receiving the Final Product (FP) from Manufacturer, FP evaluation, FP storage and issue of FP to hospital.	
Manufacturer	Receipt of SM, Manufacture CAR-T product and delivery of final product to stem cell lab or hospital / infusion site.	

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#### Keys:

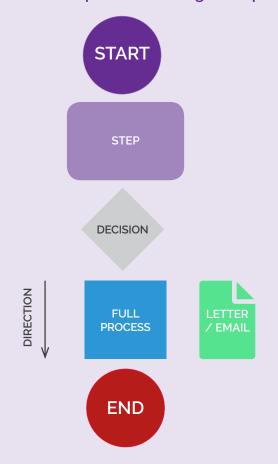
#### **Abbreviations**

SCI	Stem Cell and Immunotherapies
TAS	Therapeutic Apheresis Services
SM	Starting Material
FP	Final Product
QC	Quality Control
CAR-T cells	Chimeric Antigen Receptor T Cells
QP	Qualified person

#### Locations

Hospital/Infusion centre Stem Cells and Immunotherapies (SCI) Manufacturer

#### Process Steps / Formatting / Shapes



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