

Lunch to Learning: Unlocking the Present and Future of CliniMACS Prodigy®



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Miltényi Biotec Korea

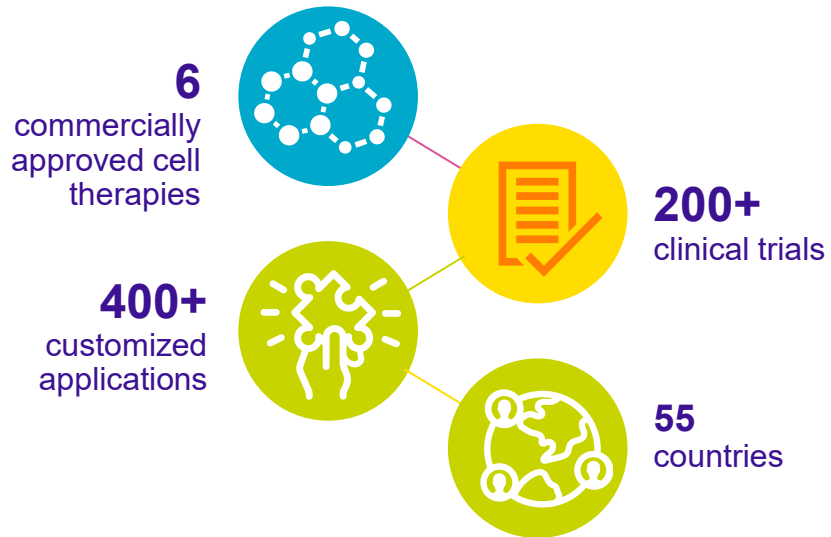
Fast facts



**Miltényi
Group**

The CliniMACS Prodigy®

Track record over 10+ years in the market



The CliniMACS Prodigy® Platform

Automation. Scalability. Flexibility.



CliniMACS® Formulation



Storage trays

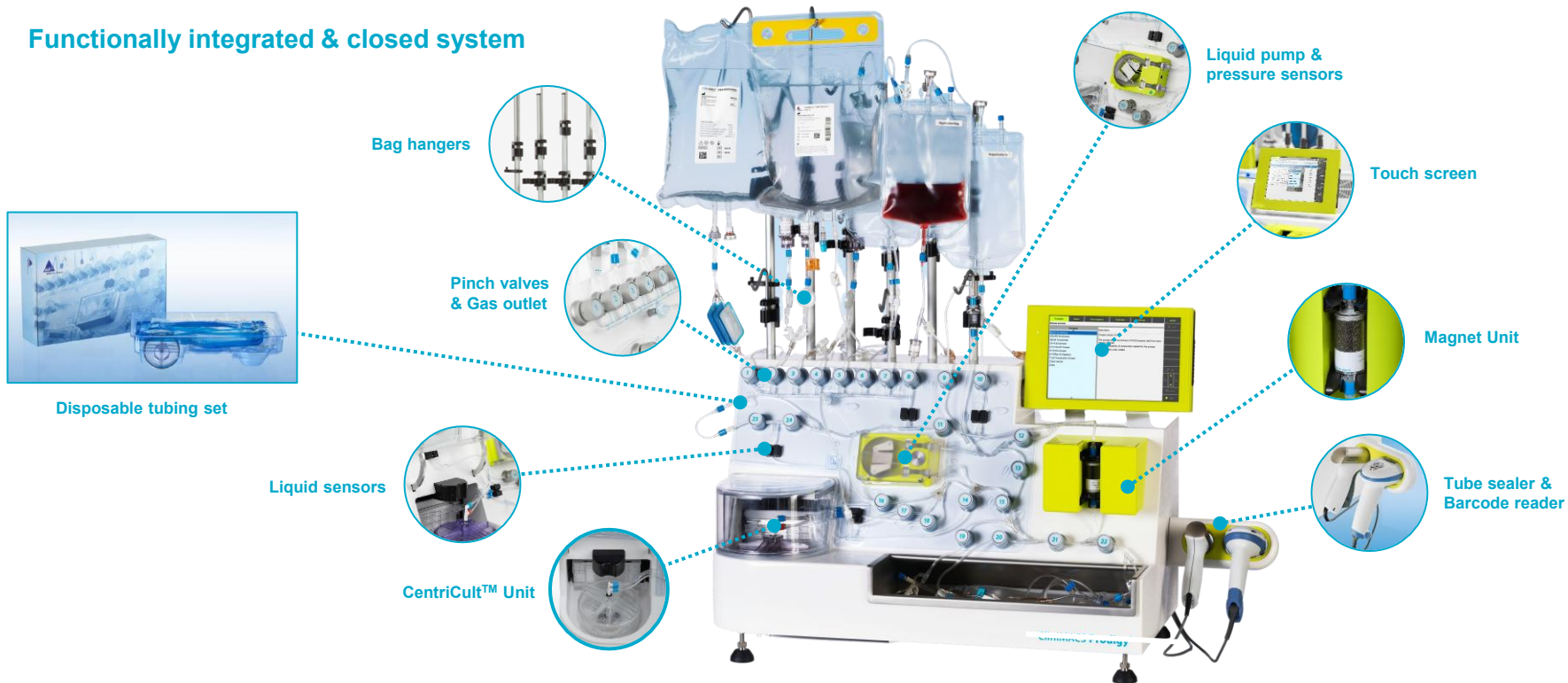


CliniMACS® Workbench

CliniMACS Prodigy® Instrument components

Integrated cell processing and data management

Functionally integrated & closed system



CliniMACS Prodigy® Instrument components

Integrated cell processing and data management



Customized Applications

Engineered T incl. CAR T cells

GMP T Cell Transduction

GMP T Cell Engineering

GMP T Cell Transduction LS

Tumor Reactive Lymphocytes

GMP Tumor Reactive T Cell process

Regulatory T cells

GMP LP-25 Pre-Enrichment

Virus-specific T cells

CE CCS (IFN γ) Enrichment

NK cells

CE LP-3-56 Separation

GMP PD-56 Engineering

GMP NK Cell Transduction (LP-3-56 + PD-56)

Engineered HSCs

CE LP-34 Enrichment

GMP HSC Engineering

PSCs and MSCs

GMP Adherent Cell Culture

Monocytes / DCs

CE LP-14 Enrichment

GMP LP-14 Mo-DC Process

GMP Blood DC Enrichment and Culture (process combination)

Graft Engineering

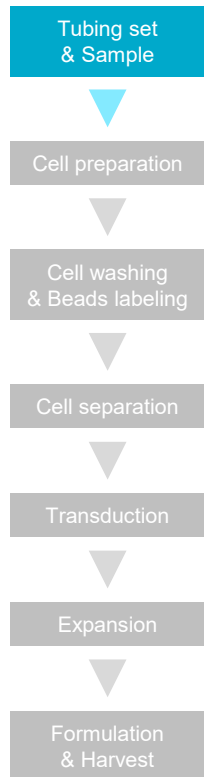
CE LP-34 Enrichment

CE LP-TCRab-19 Depletion

CE LP-TCRab-19-45RA Depletion

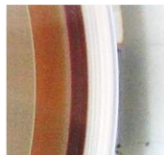
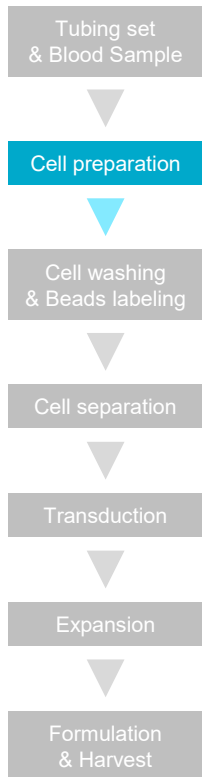
The CliniMACS Prodigy® Platform

Summary of CAR-T Process



The CliniMACS Prodigy® Platform

Summary of CAR-T Process

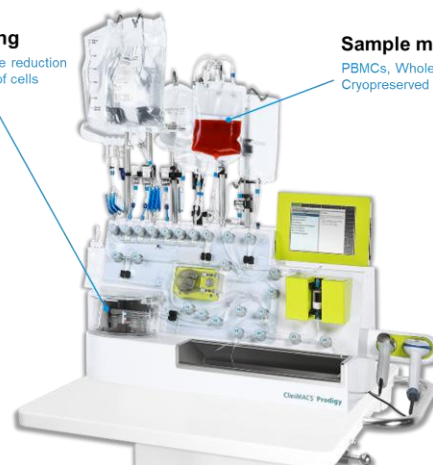


Washing

Erythrocyte reduction
Washing of cells

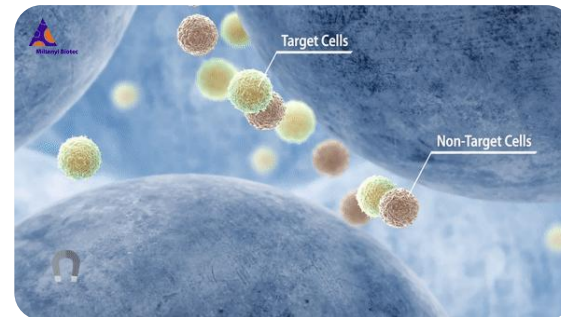
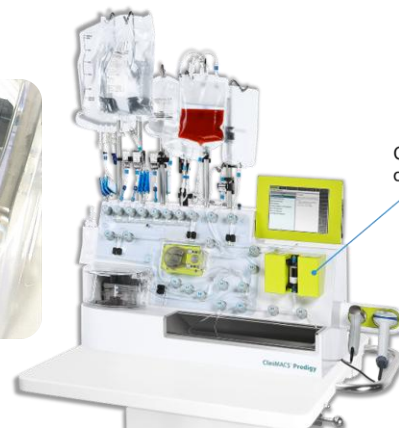
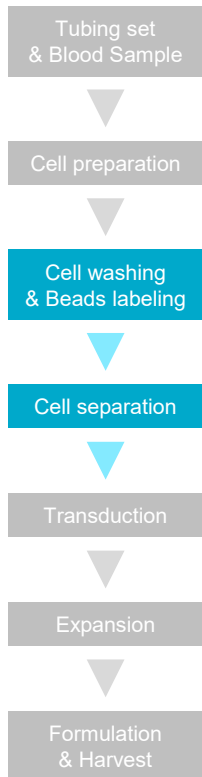
Sample material

PBMCs, Whole Blood, Leukapheresis
Cryopreserved or fresh



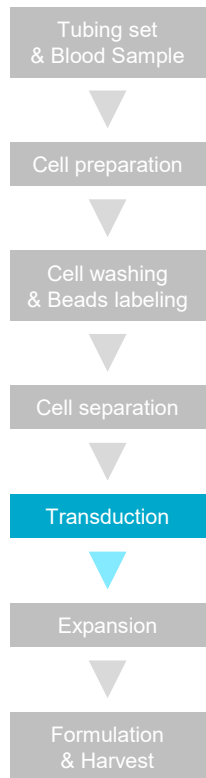
The CliniMACS Prodigy® Platform

Summary of CAR-T Process



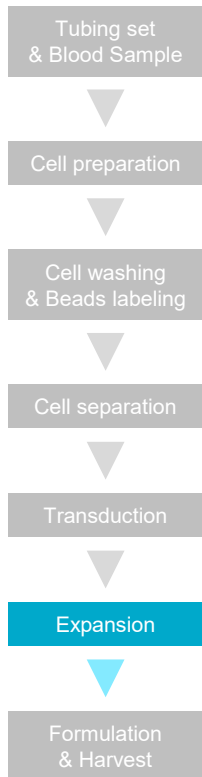
The CliniMACS Prodigy® Platform

Summary of CAR-T Process

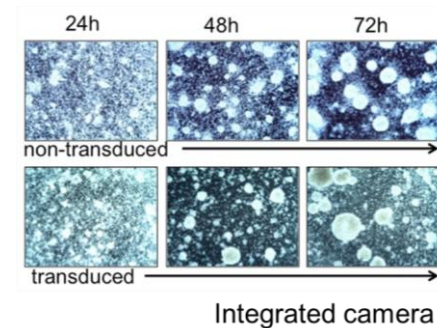


The CliniMACS Prodigy® Platform

Summary of CAR-T Process

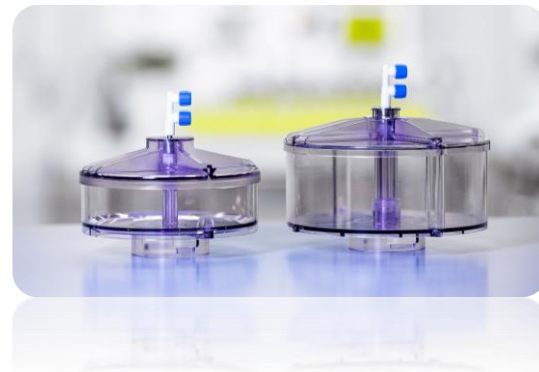
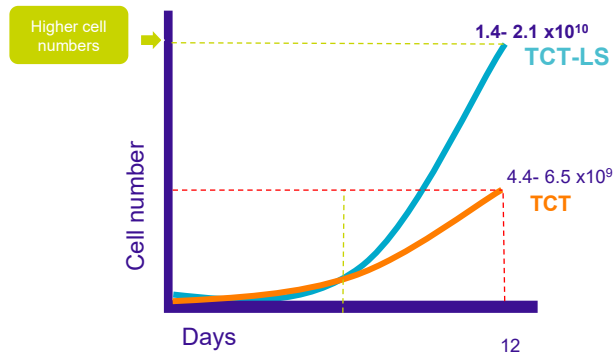
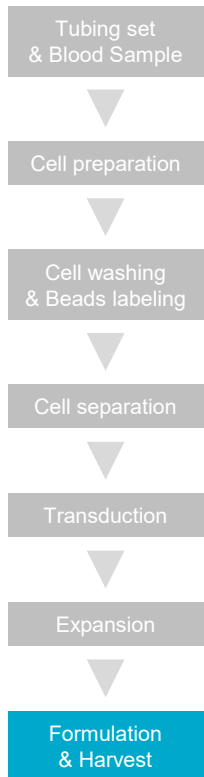


Processes	Status	User programs	Filed data	Settings	i	11:11
T Cell Cultivation - Enter activities - 7.8						
Day	Time	Activity (Parameter)	Volume			
2	10:00	Volume reduction (port: 3, vol = 50)	50			
2	10:20	Transduction (Reagent vol.: 30)	100			
2	10:30	Spin (120 min, 32 C)	100			
2	16:20	Culture wash	200			
2	17:30	Activate shaker (shake type 1)	200			
4	11:00	Media exchange (port: 3, vol (-/+): 100/150)	250			
6	10:00	Media exchange (port: 3, vol (-/+): 125/125)	250			
8	10:00	Media exchange (port: 3, vol (-/+): 125/125)	250			
10	10:00	Media exchange (port: 3, vol (-/+): 125/125)	250			
12	10:00	End of culture	250			



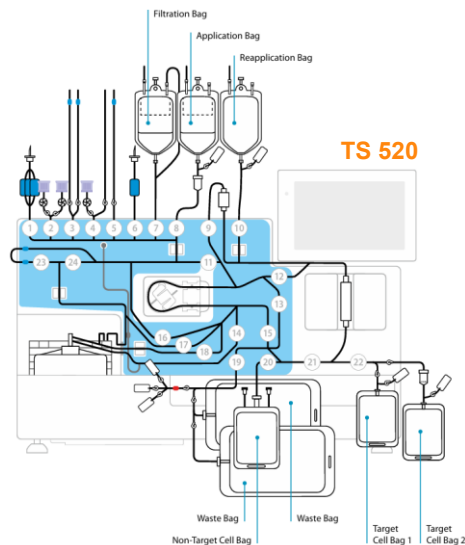
The CliniMACS Prodigy® Platform

Summary of CAR-T Process



The CliniMACS Prodigy® Platform

T Cell Transduction and Automated Formulation



Standard CAR-T Manufacturing
TCT Program + Manual Filling



+

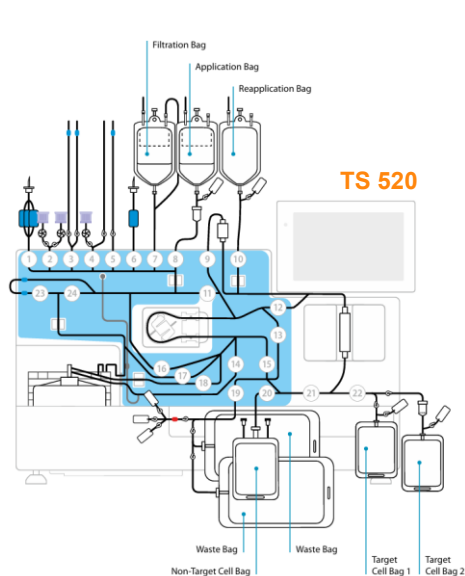


Every open step brings a risk of contamination!

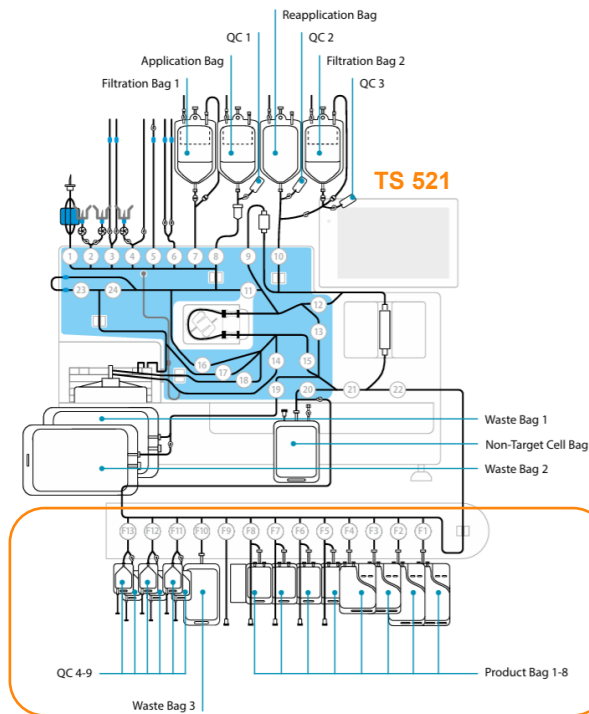


The CliniMACS Prodigy® Platform

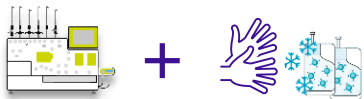
T Cell Transduction and Automated Formulation



VS



Standard CAR-T Manufacturing
TCT Program + Manual Filling



CAR-T Manufacturing with filling process
TCT Program -> automated Formulation



CliniMACS Formulation Unit



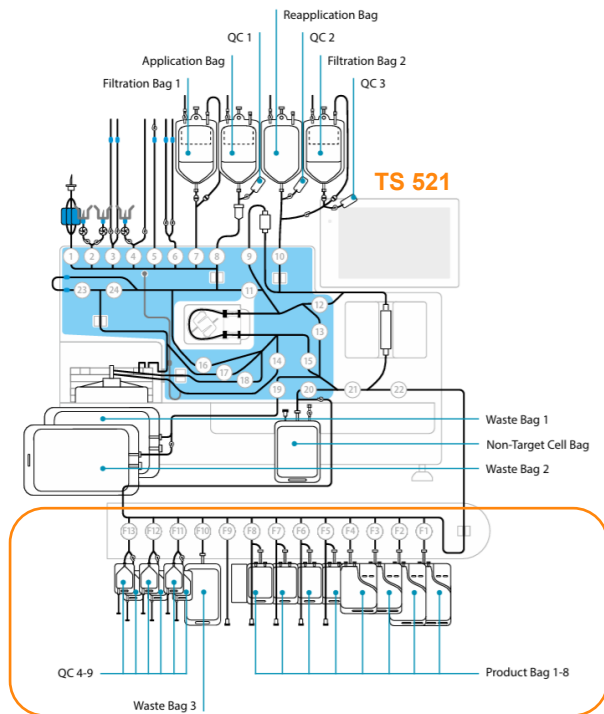
CliniMACS Formulation Solution



by closed system there is a mitigated risk of contamination
Based on the in-process control's sterility test results, manufacturer can do exceptional release of fresh products
Potential for reduced vein-to-vein time

The CliniMACS Prodigy® Platform

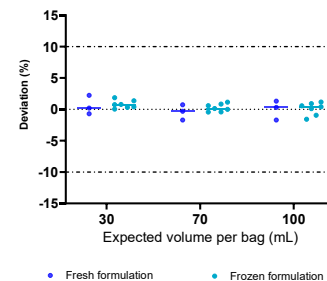
T Cell Transduction and Automated Formulation



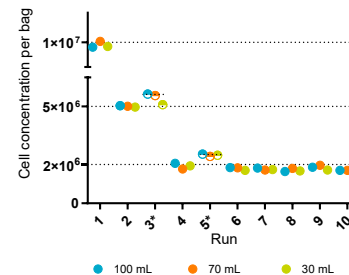
Specifications

Process name:	T Cell Transduction and Automated Formulation (TCTf)
Sample volume for selection:	50–300 mL
Selection capacity:	Up to 3×10^9 labeled cells within 20×10^9 WBCs
TransAct™ stimulation capacity:	Recommended 1×10^8 T cells
Expansion capacity:	$\sim 5 \times 10^9$ T cells in 12 days
Final product filling volume:	Up to 8 product bags
bags 1–2:	Fresh 10–300 mL / Frozen 55–100 mL
bags 3–4:	Fresh 10–250 mL / Frozen 30–70 mL
bags 5–8:	Fresh 10–50 mL / Frozen 10–30 mL
Process time:	Flexible (default: 12 days)

Automated filling of bags by volume



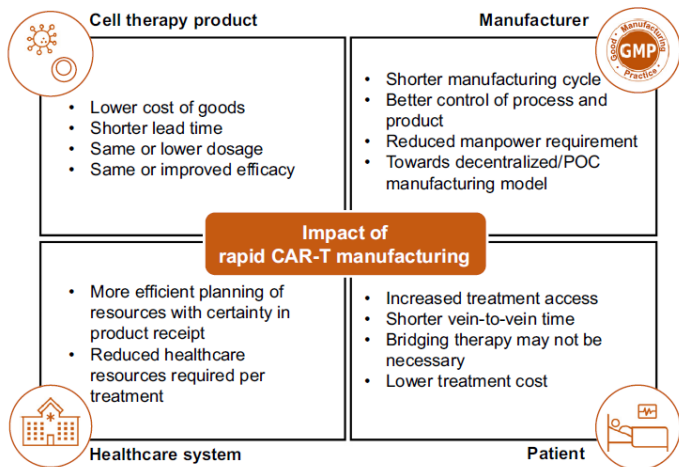
Automated filling of bags by cell conc



The CliniMACS Prodigy® Platform

Shortened CAR-T Manufacturing

Why Shorten?



Market trends

- 5-7 days well established in field
- 1-3 days already some players, quite advanced



Galapagos
7 days



BMS
5 days



UCL/Autolus
8 days



BioNtech
7 days



Immatics
7 days

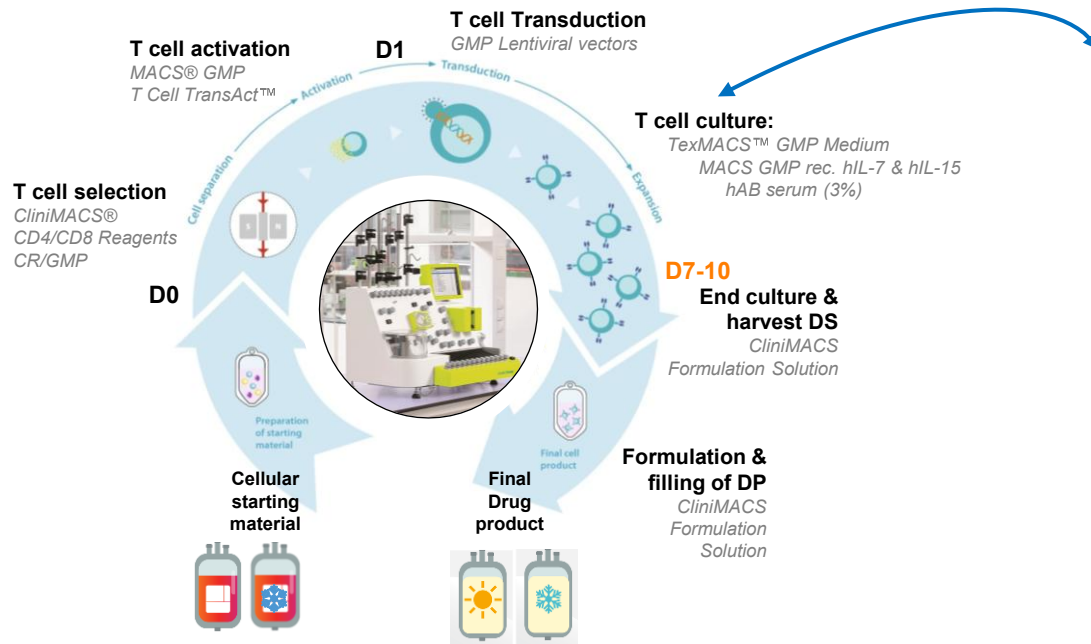


NEWS 2024

The FDA has approved a new manufacturing process change for Yescarta, Gilead's Kite Pharma unit said Tuesday. The approval allows the company to shorten the CAR-T cell manufacturing time for Yescarta from an average of seven days to five days, Chris McDonald, Kite's head of technical operations, told Fierce Pharma.

The CliniMACS Prodigy® Platform

Shortened CAR-T Manufacturing



Day	Activity	Note
0	Activation	As part of culture set-up
1	Lentiviral Transduction	With a defined MOI of 5
3	Culture wash	2 cycles
3	Activate shaker	Type 2
5	Medium exchange	Remove 50 mL / add 50 mL
6	Medium exchange	Remove 130 mL / add 130 mL
6	Activate shaker	Type 3
6	Medium exchange	Remove 130 mL / add 130 mL
7	Harvest	In CliniMACS Formulation Solution

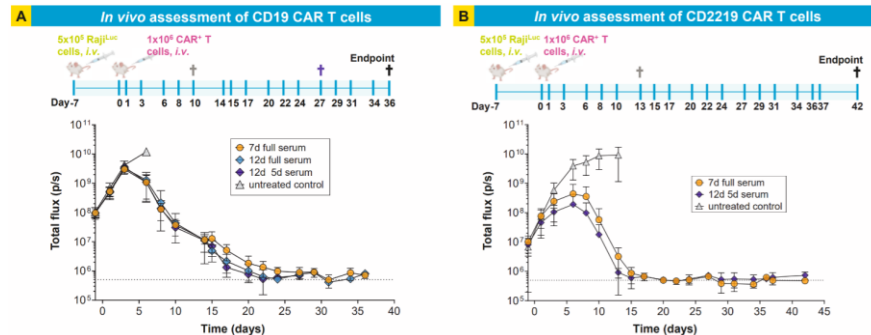
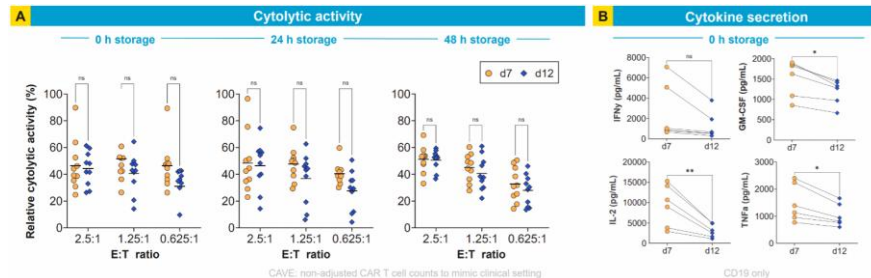
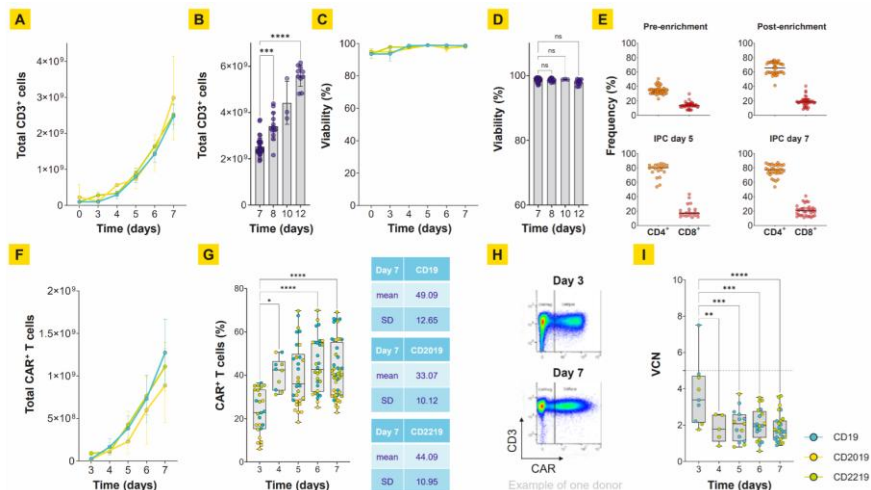
For Harvest on Day 8

7	Medium exchange	Remove 130 mL / add 130 mL
8	Harvest	In CliniMACS Formulation Solution

For Harvest on Day 10

7	Medium exchange	Remove 130 mL / add 130 mL
8	Medium exchange	Remove 130 mL / add 130 mL
8	Medium exchange (+12h)	Remove 130 mL / add 130 mL
9	Medium exchange	Remove 130 mL / add 130 mL
10	Harvest	In CliniMACS Formulation Solution

The CliniMACS Prodigy® Platform Shortened CAR-T Manufacturing



In conclusion, this fast and flexible CAR T cell manufacturing on the CliniMACS Prodigy® can significantly enhance the accessibility and operational facilitation of CAR T cell therapies across diverse clinical settings.

The CliniMACS Prodigy® Platform

Bringing Lipid Nanoparticles (LNPs) to the CliniMACS Prodigy



Integrated into the CliniMACS Prodigy® workflow, the **CliniMACS Electroporator** enables flexibility in large-scale transfection of various cell types



Automated & closed: Fully automated electroporation in closed tubing set for increased standardization and product/operator safety



Full control: Flexible electroporation parameters (e.g., pulses, duration, intensity) that works best for different cell types, allowing combination of electroporation and viral transduction

Transduction

- Lentiviral vector
- Retroviral vector

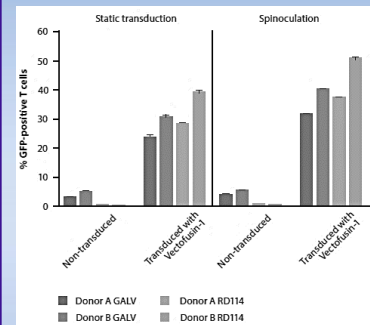


Electroporation

- Plasmid
- mRNA/ siRNA
- Crispr/Cas
- Zinc finger
- TALENs
- Sleeping Beauty

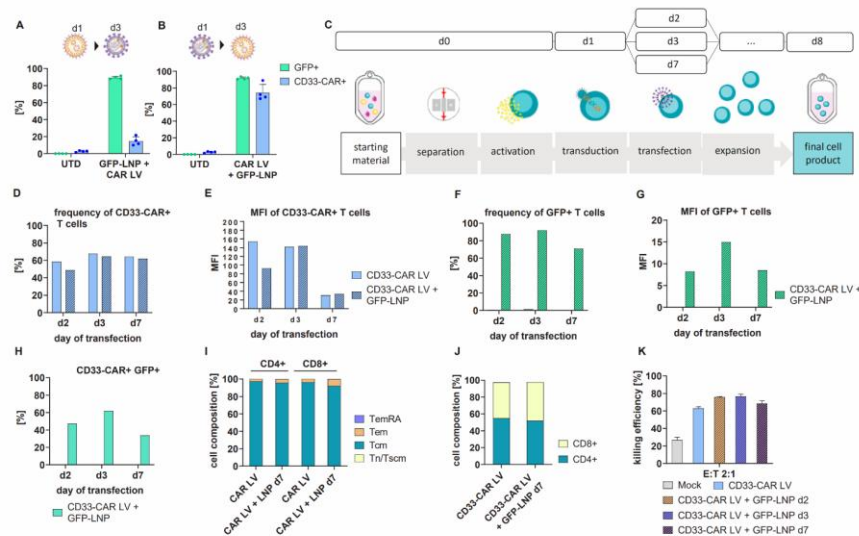
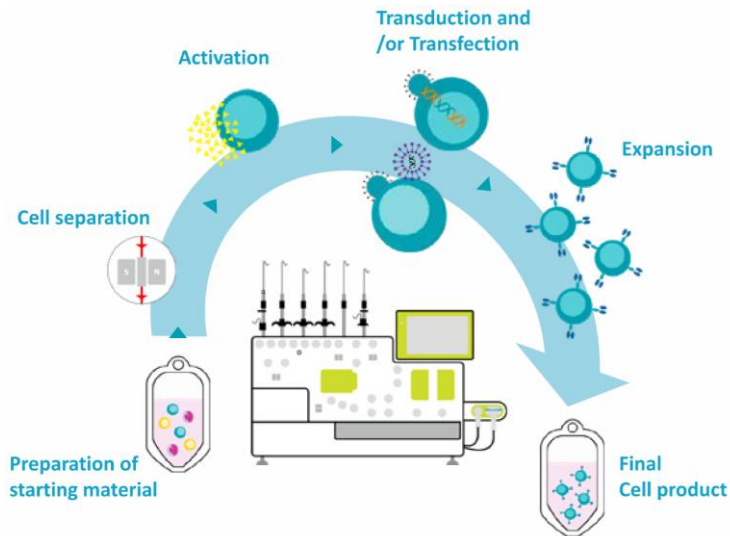


Lentiviral and retroviral transduction

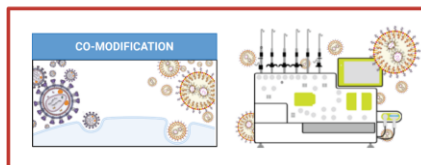
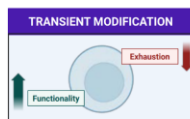
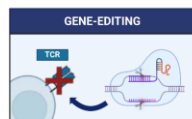


The CliniMACS Prodigy® Platform

Bringing Lipid Nanoparticles (LNPs) to the CliniMACS Prodigy



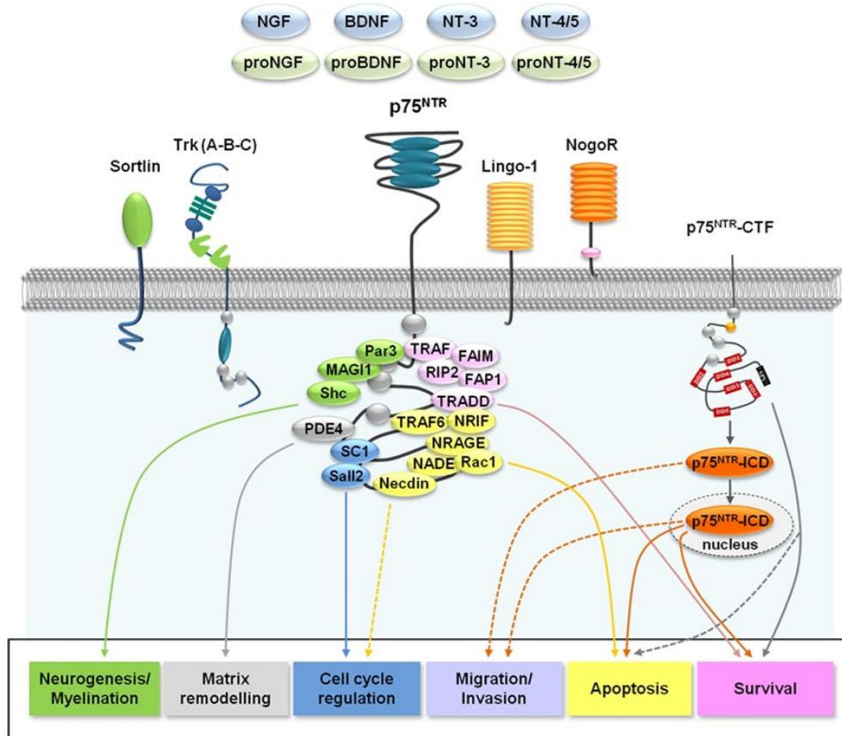
AUTOMATED MANUFACTURING



The manufacturing of LNP co-modified CD33-CAR T cells generated a potent cell product with a clinically favorable early phenotype and high cytolytic potential against AML tumor cells.

The CliniMACS Prodigy® Platform

LNGFR (CD271) a new marker for cell selection



Cell. Mol. Life Sci. 71, 2467–2481 (2014).

CD271

= NGFR (Nerve Growth Factor Receptor)

= LNGFR (Low-affinity Nerve Growth Factor Receptor)

= p75 Neurotrophin Receptor (p75^{NTR})

CD271 is a **member of the TNF receptor superfamily** that lacks enzymatic activity (such as kinase activity) on its own.

It activates completely different downstream signaling pathways depending on the co-receptors it partners with and the type of ligand involved.

In the neural system,

CD271 is involved in **neuronal survival, differentiation, axonal growth, and apoptosis.**

In bone marrow, it contributes to the **self-renewal and maintenance of multipotency in MSCs.**

Therefore, CD271+ MSCs are widely used as a marker for high stemness in MSC populations.

It is also associated with **bone regeneration.**

The CliniMACS Prodigy® Platform

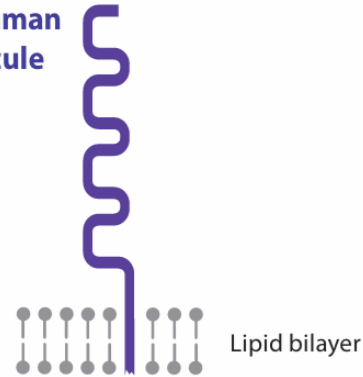
LNGFR (CD271) a new marker for cell selection

truncated LNGFR (tLNGFR)

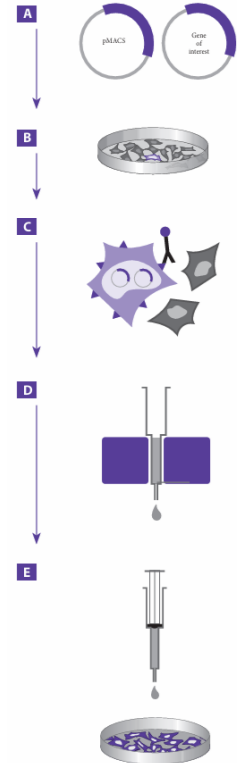
LNGFR is a **Non-immunogenic** marker.

Used in a truncated form (tLNGFR) as selection marker for gene-engineered cells (e.g., HSCs, CAR T cells, ...)

Truncated human LNGFR molecule

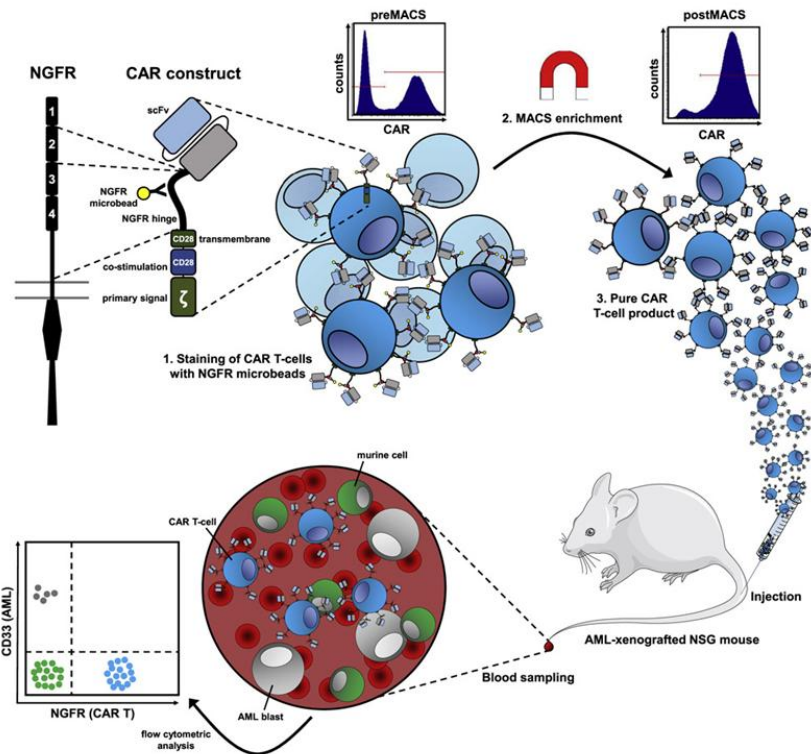


Non-signaling truncated receptor



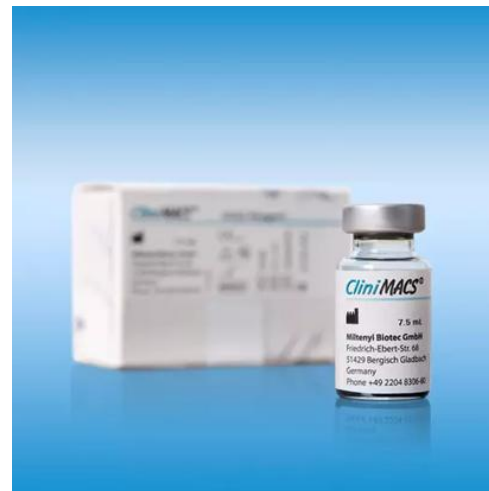
The CliniMACS Prodigy® Platform

LNGFR (CD271) a new marker for cell selection



CliniMACS® CD271 Product Line

CD271, also known as LNGFR (low-affinity nerve growth factor receptor), NGFR or p75NTR, belongs to the low-affinity neurotrophin receptor and the tumor necrosis factor receptor superfamily.



The CliniMACS Prodigy® Platform

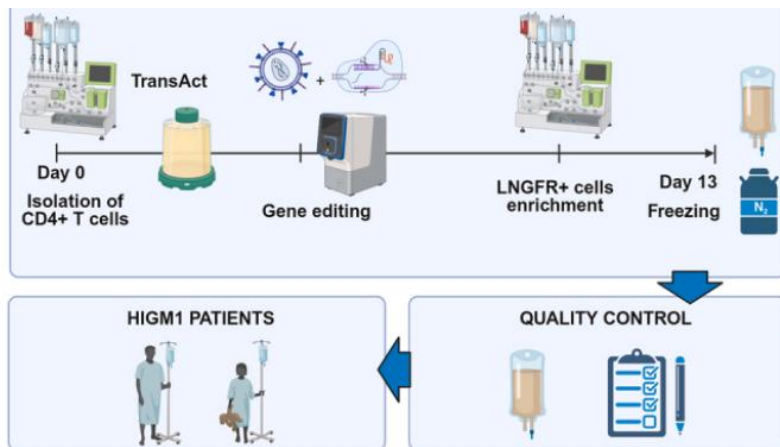
LNGFR (CD271) a new marker for cell selection

Molecular Therapy
Methods & Clinical Development
Original Article

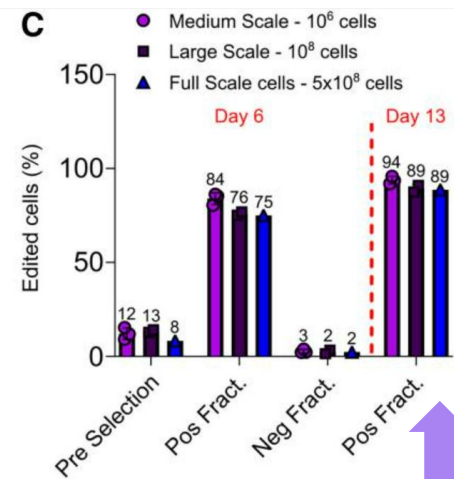
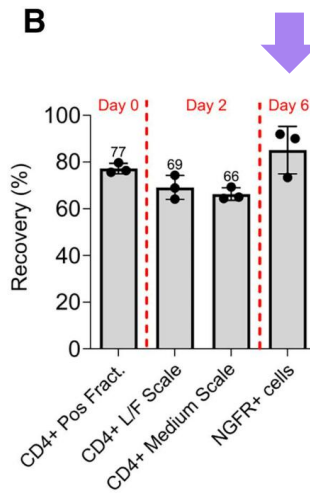


Scalable GMP-compliant gene correction
of CD4+ T cells with IDLV template functionally
validated *in vitro* and *in vivo*

Claudia Asperti,^{1,10} Daniele Canarutto,^{1,2,3,10} Simona Porcellini,¹ Francesca Sanvito,^{1,4} Francesca Cecere,¹
Valentina Vavassori,¹ Samuele Ferrari,¹ Elisabetta Rovelli,¹ Luisa Albano,¹ Aurelien Jacob,¹ Lucia Sergi Sergi,¹
Elisa Montaldo,¹ Francesca Ferrua,^{1,3} Luis Ignacio González-Granado,^{5,6} Vassilios Lougaris,⁷ Raffaele Badolato,⁷
Andrea Finocchi,⁸ Anna Villa,^{1,9} Marina Radrizzani,^{1,11} and Luigi Naldini^{1,2,11}



Good recovery ~
80% average



Good purity
89% average full scale

The CliniMACS Prodigy® Platform

LNGFR (CD271) a new marker for cell selection



CELL & GENE THERAPY INSIGHTS

Scaling smarter: a case study in overcoming cell therapy manufacturing and regulatory hurdles

Wednesday 15th October 2025

08:00 PDT / 11:00 EDT / 16:00 BST / 17:00 CEST



James Adams, MBA
Chief Technical
Officer
Tr1X Inc.
View Biography

Tr1X Bio webinar highlighting the cooperation with **Milenyi Bioindustry**.



Achieve exceptional product purity

A CD271-based purification approach enabled 95–98% purity
—exceeding typical industry benchmarks.

Miltenyi Biotec
Thank you for your attention!



Start your CGT journey
with CliniMACS Prodigy.

