

# Miltenyi Biotec in Cell & Gene Therapy

## Empowering Discovery. Advancing Therapy.

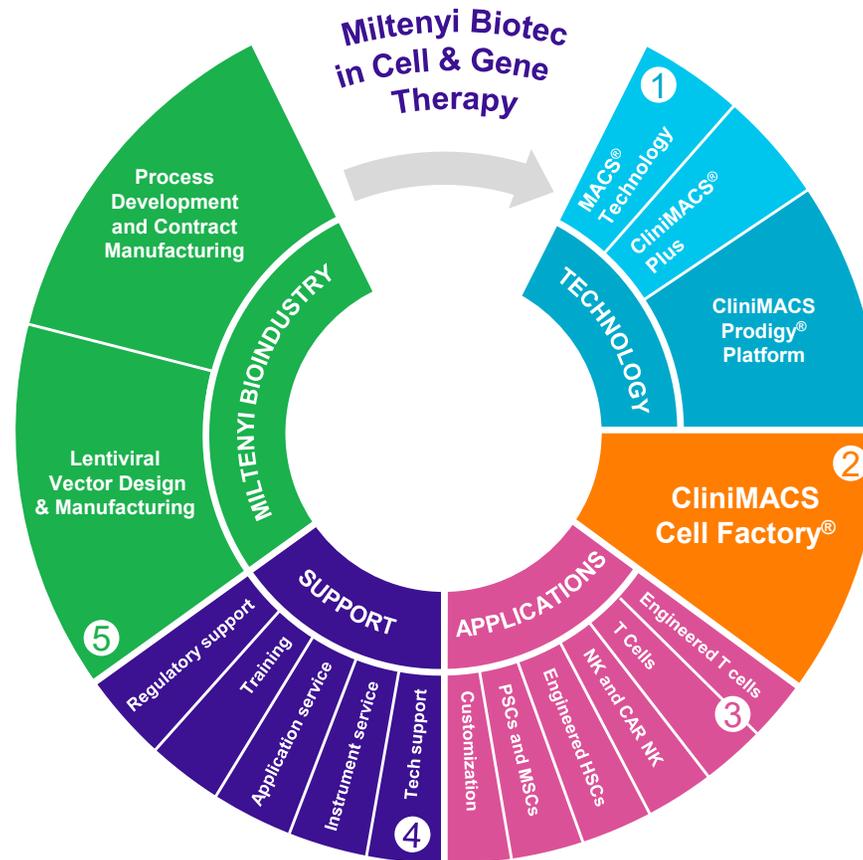


Non-confidential customer presentation



# Miltenyi Biotec

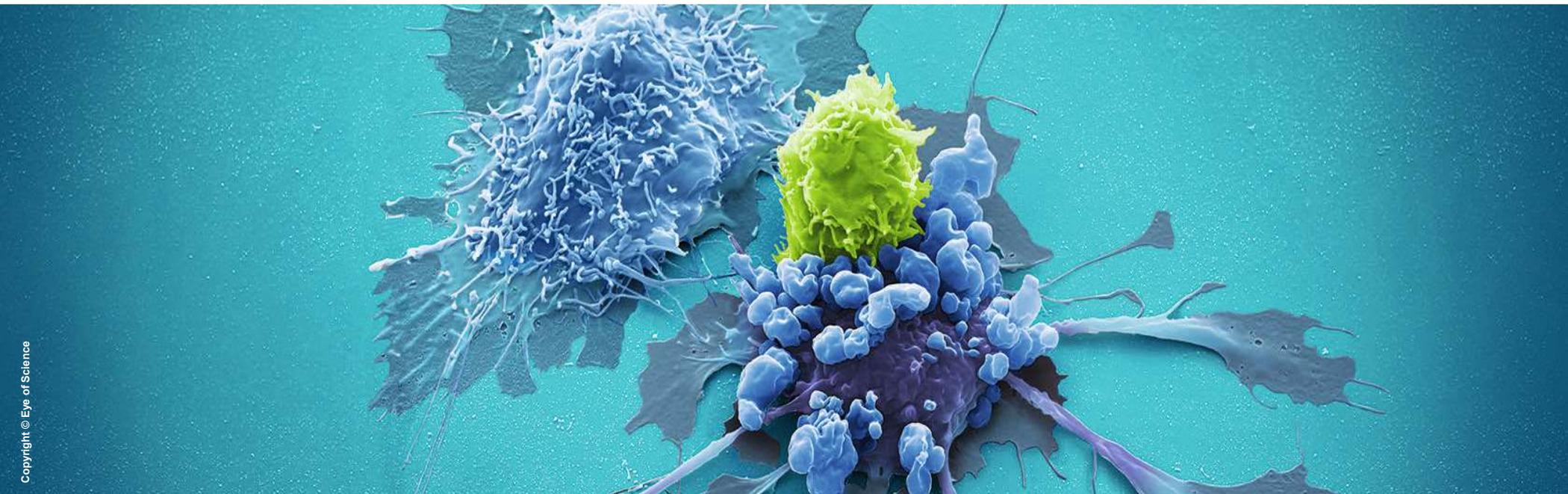
## Your partner in Cell & Gene Therapy



# Empowering discovery. Advancing therapy.



**Our mission is to advance scientific research and medicine by providing solutions for curative cell and gene therapy as well as biomedical research.**



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# Our values

## From excellence and innovation to creativity



### Excellence

We live our culture of excellence, from R&D and engineering to production and support. The superior quality of our products comes from more than three decades of experience and engineering. As researchers ourselves, we share a scientific mindedness with our customers.



### Innovation

We provide pioneering innovations and technology leadership to our customers, opening up new opportunities in research and cell therapy. We have a strong will to change things for the better, by continuously pursuing the path to new medical treatment options to fight serious diseases.



### Creativity

We dare to be different, to swim upstream. Our creative engine is the diversity inside the company. We are independent. Free from the limitations of “profit first” shareholder oversight. We account to no one but ourselves and our customers.

# Fast facts

## Miltenyi Biotec in a nutshell



**1989**

Foundation  
in Germany



**> 3,900**

Employees  
worldwide



**50**

Nationalities  
within our staff



**25%**

Employees in  
global R&D



**> 46,000**

Scientific  
References  
(Google Scholar; 01/ 2021)



**> 17,000**

Products



**> 100,000**

Cell therapy  
procedures with  
Miltenyi Biotec  
products



**6,000 p.a.**

Patients treated  
with cell products  
using our technologies



**23**

Countries with  
direct sales



**73**

Countries served  
including distributors

# Miltenyi Biotec presence GMP facilities, offices, and distributors



# History of acquisitions and expansions

## Key technologies and locations



**2014**  
MEMS chip technology



**2017**  
Adapter CAR T technology



**2019**  
Next Generation Sequencing



**1989**  
Foundation of Miltényi Biotec



**2002**  
Teterow GMP manufacturing facility



**2019**  
SciVis Scientific image processing

**1994**  
Amcell Amgen joint venture



**2014**  
Lentiviral vector technology



**2008**  
Medic Tools Sample preparation technology



**2017**  
Advanced optical technology



**2018**  
Advanced optical technology



**2021**  
CliniMACS Cell Factory® opening



# Three decades of pioneering solutions

## Clinical product portfolio



Cell separation

Sample preparation

Flow cytometry

Cell culture

Imaging

Clinical products



**1997**  
CliniMACS® Plus



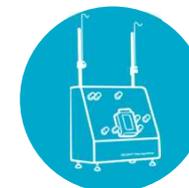
**2008**  
CryoMACS® Freezing Bags



**2012**  
MACS® GMP Media



**2016**  
CliniMACS Prodigy®



**2021**  
CliniMACS®  
Electroporator



**2002**  
LIFE 18™ Apheresis Unit



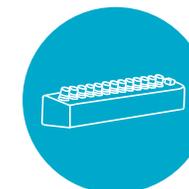
**2008**  
MACS® GMP Cytokines



**2016**  
Lentigen's Lentiviral  
vector



**2018**  
LIFE 21™ Apheresis  
Unit



**2021**  
CliniMACS®  
Formulation Unit

# Product spectrum

## Integrated workflows



# Product portfolio

## From benchtop to bedside



Sample preparation



Cell isolation



Cell activation/  
expansion



Cell culture



Cell analysis



Imaging

**BENCHTOP**



**BEDSIDE**

Cryo-preservation



Cell analysis



Cell culture



Cell activation/  
expansion



Cell processing

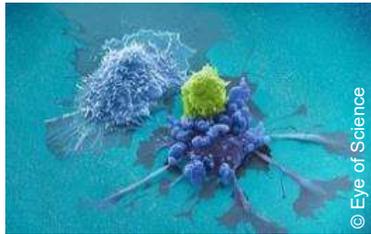


# Product portfolio

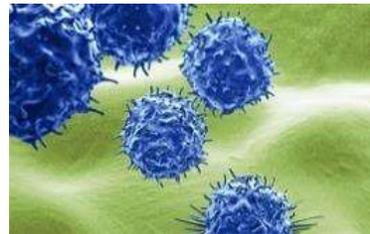
## From research to clinical applications



Immunology



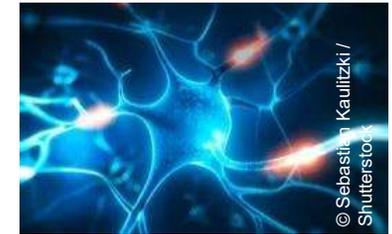
Cancer research



Stem cell research



Cardiovascular research



Neuroscience

RESEARCH

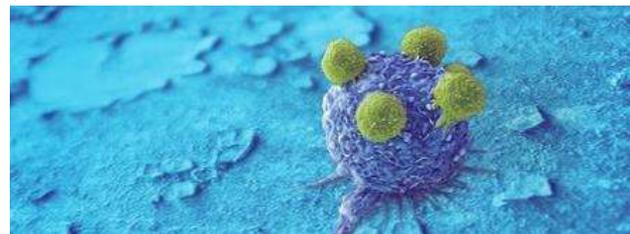


CLINICAL

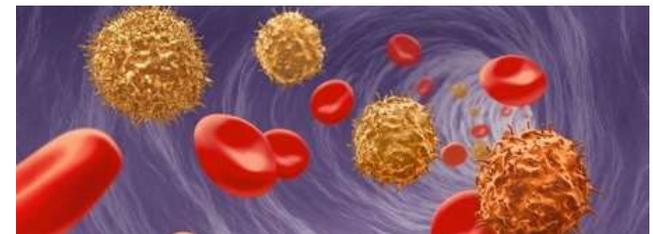
Graft engineering



Immunotherapy



Regenerative medicine



# The experts in cell and gene therapy

## Certified and clinically proven products



### Certified to meet commercial needs for the clinic

- Certified as a pharmaceutical manufacturer
- GMP manufacturing license for monoclonal antibodies
- Certified quality management system in place (i.e. ISO 13485 and ISO 9001)
- Relevant regulatory support files and standards available (e.g. PIF, CoA, CoO/TSE)

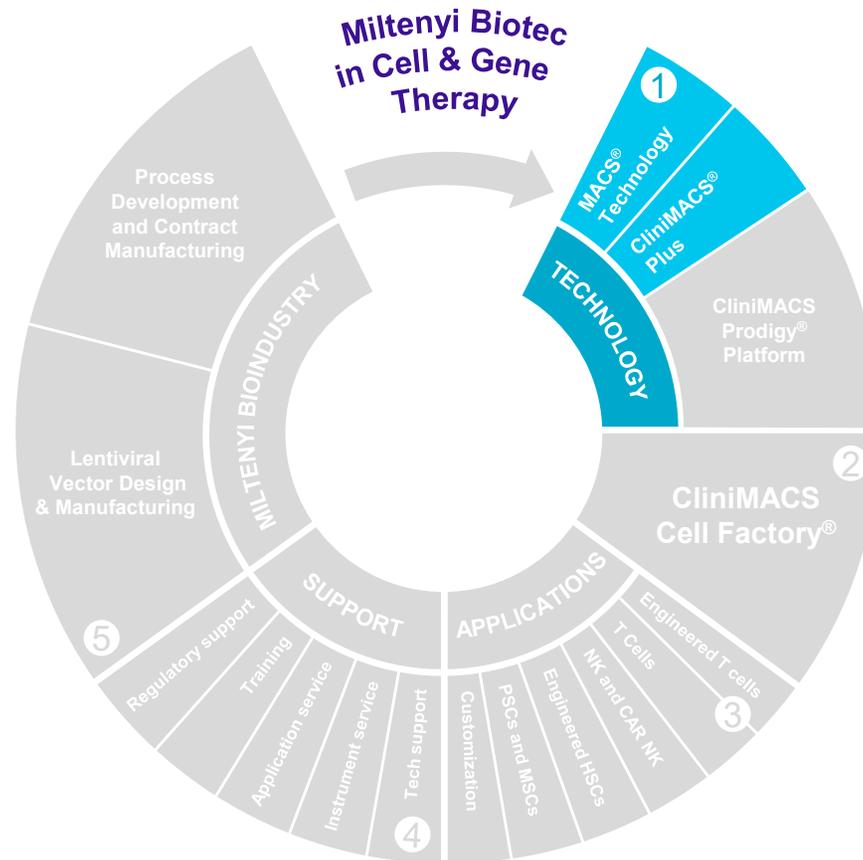


### Proven clinical concepts

- FDA-approved CliniMACS<sup>®</sup> CD34 Reagent System
- Annually, more than 6,000 patients receive cell products manufactured with Miltenyi Biotec technologies
- More than 500 INDs/IDEs at US FDA
- 150+ clinical studies in EU & ROW
- 30+ Type II Master files at US FDA
- 33+ applications for cell separation (CE-marked) and 8+ cell manipulation (GMP) in the EU

# Your partner in Cell & Gene Therapy

## MACS® Technologies



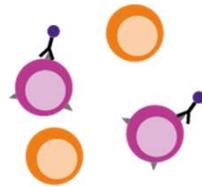
# MACS<sup>®</sup> Technology

## Starting with a well-defined cell population



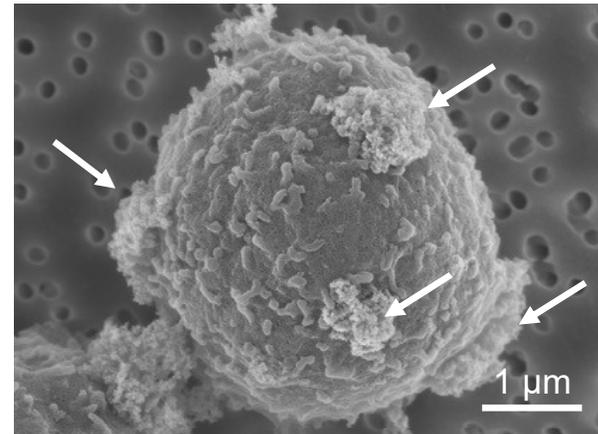
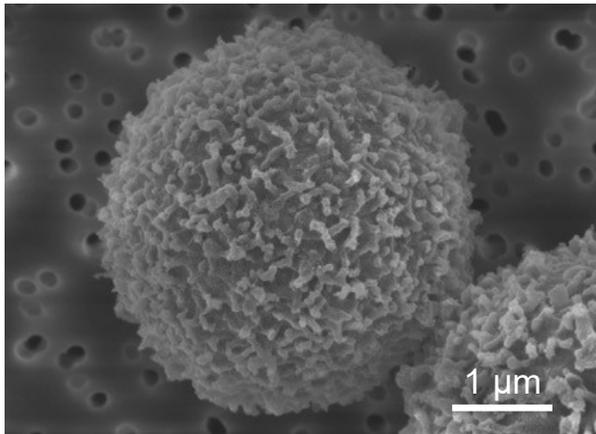
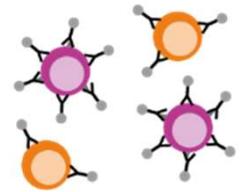
### Advantage of column-based technology

- ✓ Strong magnetic force
- ✓ Minimal labeling suffices
  - No non-specific labeling
  - No cell activation
  - No alteration of characteristics



### Disadvantage of column-free technologies

- Weak magnetic force
- Massive labeling required
  - Non-specific labeling
  - Cell activation
  - Alteration of cell characteristics



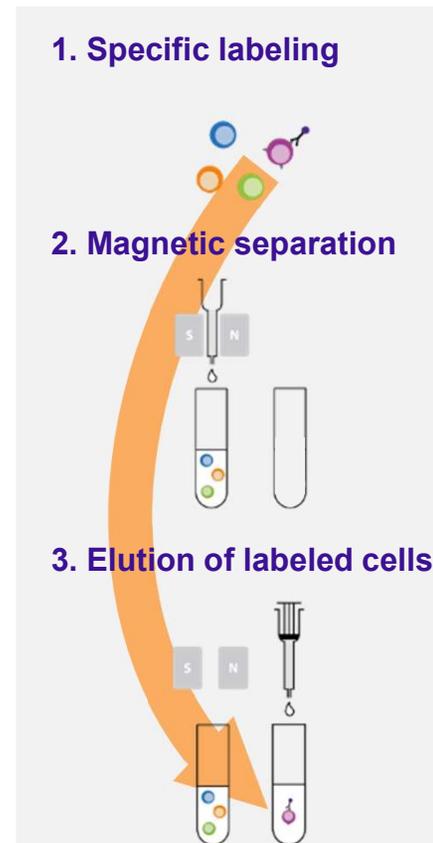
# MACS® Columns

## Separating labeled and unlabeled cells

### Integrated cell enrichment or depletion step

- CliniMACS Separation Column provides **commercial-scale cell enrichment or depletion** by using surface markers
- **Positive selection**
  - > Cells of interest are labeled and retained in column
  - > Non-target cells flow through
  - > Magnet is turned off and cells of interest are eluted to Target cell bag
- **Negative selection**
  - > Non-target cells are labeled and retained in column
  - > Target cells flow through to Target cell bag
  - > Magnet is turned off and non-target cells are eluted

### Principle



# The instrument that started it all

## CliniMACS® Plus

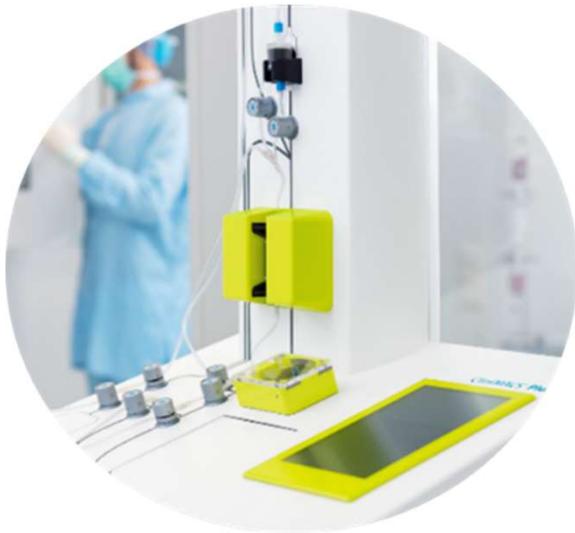


### Functions and features

- A **functionally closed and automated** cell separation system
- **Enrichment** of target cell types or **depletion** of unwanted cells
- Separation of large numbers of cells providing target cells with **high purity and excellent yield**
- Supports a wide range of automated cell separation applications
- **Certified medical device**, compatible for use in a GMP setting

### FDA approval – The CliniMACS® CD34 Reagent System

- FDA-approved method for selecting hematopoietic stem cells from donor apheresis, while passively depleting T cells that can cause graft-versus-host disease (GVHD).
- Treatment of patients with acute myeloid leukemia (AML) in first complete remission



# CliniMACS® Plus

## Examples of applications



### Selection of different applications

- **T cell isolation:** CD4/CD8 positive selection
- **T cells:** TCR a/b depletion
- **NK cells:** CD3 depletion / CD56 enrichment
- **Treg isolation:** CD25 enrichment
- **B cells:** CD19 depletion or enrichment
- **HSC isolation:** CD34 enrichment



### Key benefits



- ✓ Closed cell separation
- ✓ Automated and standardized
- ✓ High purity and excellent yield

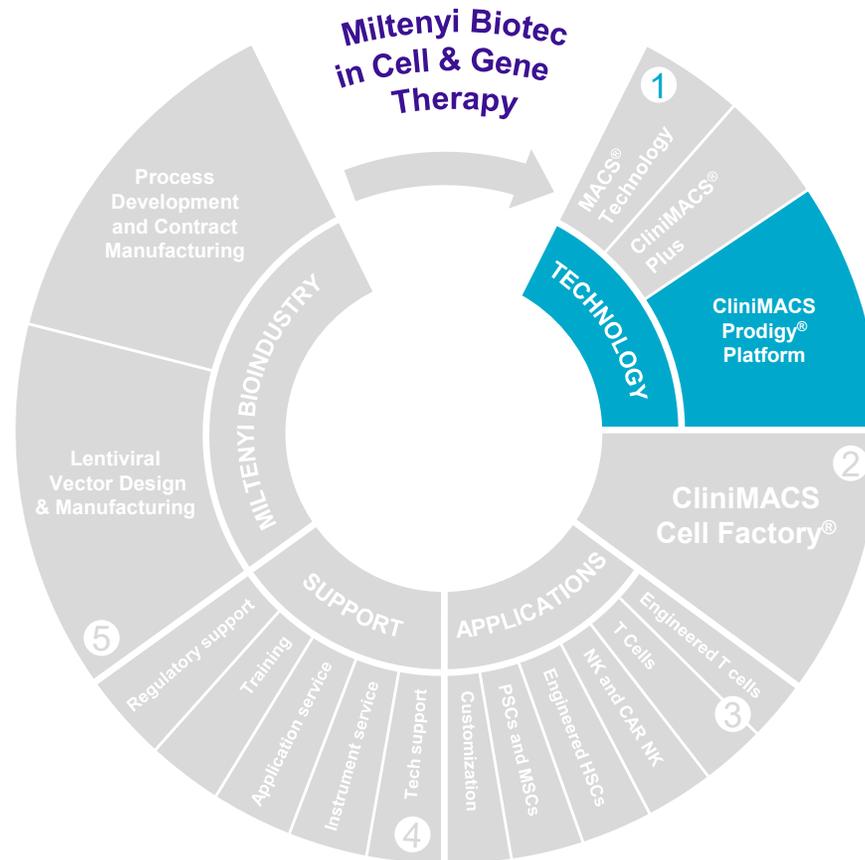
# Track record

## The CliniMACS® Plus in worldwide use



# Your partner in Cell & Gene Therapy

## CliniMACS Prodigy® Platform



# Manual cell processing

## Multiple process steps bear unintended risks & costs



### Representative CAR T procedure



#### Product risk and failures

- > 20 transfers and manual handling steps
- Many devices and windows for variability and error

#### Increased operational and capital expenditure

- Open steps require high cleanroom requirements
- Labor intensive with highly skilled staff
- Several devices require different protocols, multiple IQ/OQ's and service contracts
- Disconnected data flow and recording



# From manual operation to automation

## Reduces costs and lowers need for multiple devices



### CliniMACS Prodigy® Platform



We provide a **hands-off, end-to-end process platform** to master the complexity of your cell processing from R&D to commercial scale.

### Key features

- ✓ **Integrated, flexible platform** as an all-in-one solution with one closed consumable and reduced footprint
- ✓ **Fully automated platform** for increased reproducibility standardization from R&D to commercial scale
- ✓ **Closed system with in-process control and quality control (IPC/QC) sampling** for increased process robustness
- ✓ **Flexible software and parameterization** within standardized process
- ✓ **CliniMACS Prodigy Platform used in 180+ clinical studies**



# CliniMACS Prodigy® Platform

## Key benefits



### Flexibility

- Multiple pre-installed, clinically proven applications available with configurable parameters
- Customized application (CAP) services to meet specific process parameters and regulatory requirements
- Specialized and optimized pre-assembled tubing sets to allow flexibility



### Scalability

- One device for any scale: Reduced development and regulatory risks towards commercial scale
- Closed and integrated system for reduced cleanroom space
- Full automation for reduced operational expenditure (OPEX)
- Allows commercial scale-out by parallelization



### Consistency in product quality

- Clinically proven system and GMP-enabling applications that meet all regulatory requirements
- Automation for standardized and reproducible procedures
- GMP-compliant processing with automated logs and protocols
- Closed system reduces the risk of contamination
- Reliable supply, full service and regulatory support



# CliniMACS Prodigy® Platform

## Proven platform for Cell & Gene Therapy



# CliniMACS Prodigy<sup>®</sup> track record

## List of selected publications and clinical studies



Latest reference list

**46** +  
SCIENTIFIC PAPERS  
& REPORTS

### Manufacturing optimization & pre-clinical data:

- Different enrichment strategies (CD62L and CD4/CD8), cultivation strategies (IL-2 and IL-7/IL-15) and transduction strategies (retrovirus and lentivirus) ([Mock, 2016](#); [Priesner, 2016](#))
- Fresh and frozen starting product ([Shah, 2020](#))
- Shortening CAR T process to 8 days ([Zhang, 2019](#))
- IPC, QC, functional tests, phenotyping ([Mues, 2020](#))
- Combined in-line electroporation and lentiviral delivery ([Alzubi, 2020](#))

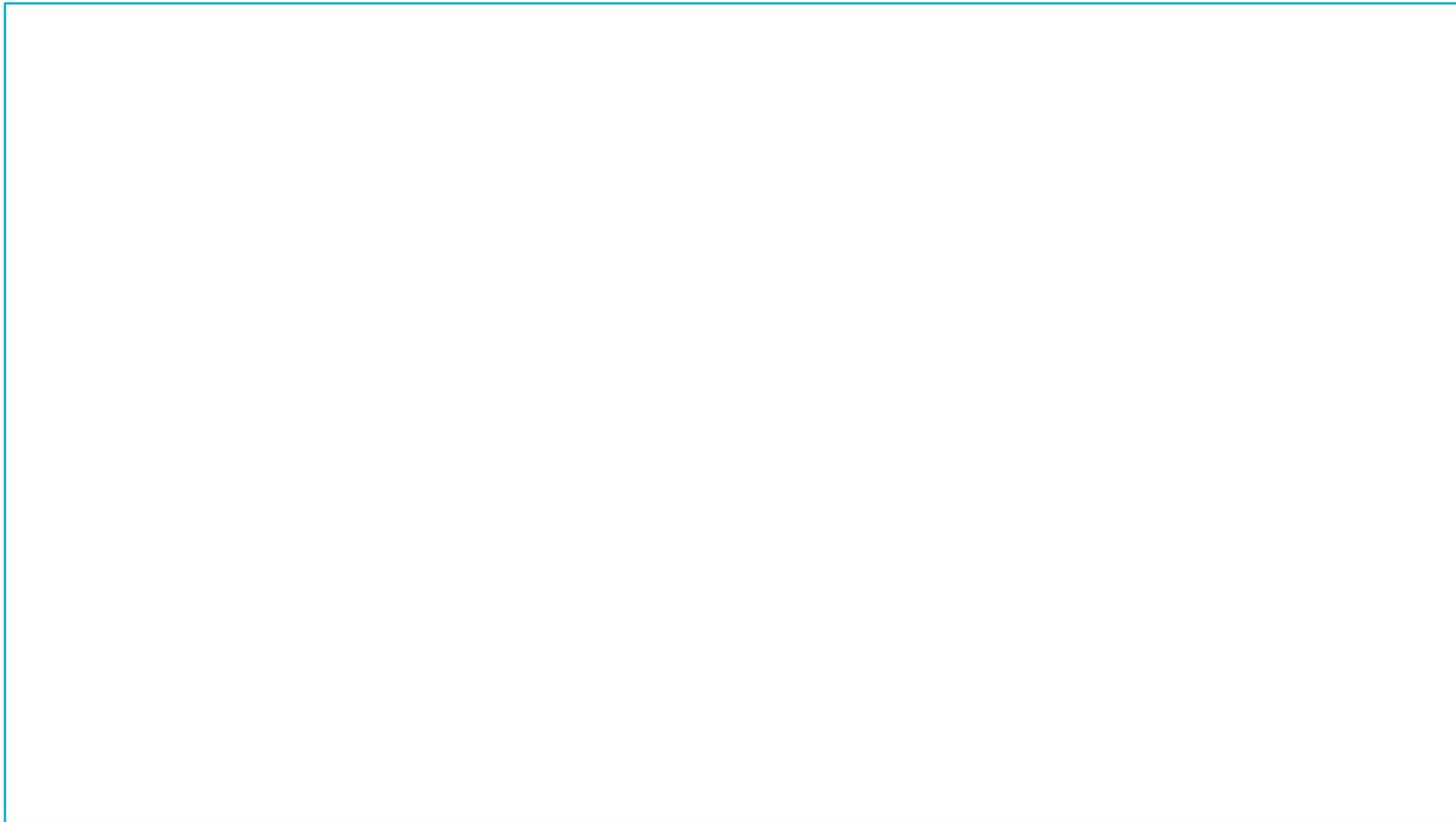
**180** +  
CLINICAL TRIALS  
WORLDWIDE

### Phase I/II clinical trial studies:

- Bispecific anti-CD20/anti-CD19 CAR-T for relapsed B-cell malignancies ([NCT03019055](#))
- Autologous CD19 CAR-T for NHL ([NCT03434769](#))
- Switchable universal CAR-T for CD123-positive leukemia ([NCT04230265](#))
- Activated NK cells for sarcomas ([EudraCT 2016-003578-42](#))
- Antigen-specific T Cell Therapy for AML or MDS patients ([NCT04284228](#))
- Antigen-specific T cell therapy for myeloma ([NCT04505813](#))

# CliniMACS Prodigy<sup>®</sup> Instrument

## Automated cell processing in a closed system

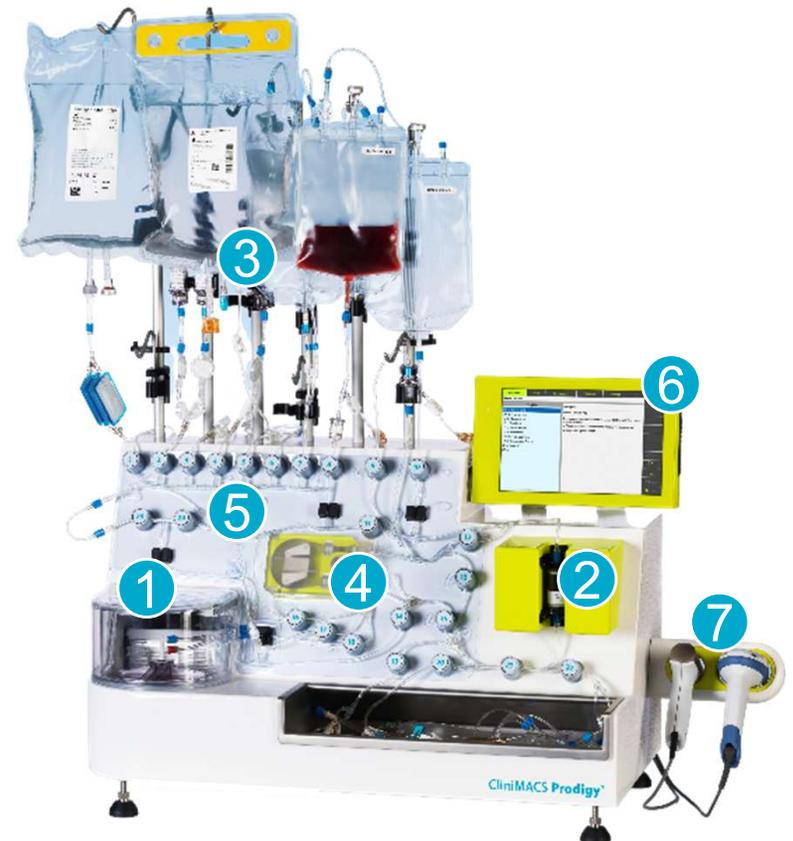


# CliniMACS Prodigy<sup>®</sup> Instrument components

## Integrated cell processing and data management



1. **CentriCult™ Unit (CCU):** Controlled unit for cell preparation, processing and cell cultivation with integrated camera
2. **Magnet unit:** Houses separation column for magnetically labelled cell enrichment/depletion
3. **Tubing set:** Allows closed and aseptic processing and sample take for in-process control and quality control
4. **Peristaltic pump:** Directs accurate volumes of liquids through closed tubing set for automatic processing
5. **Gas mixing unit:** Mixes up to three gases for optimal cell cultivation in the CCU
6. **Touchscreen and software:** Customizable software guides user through the process.
7. **Tube sealer and bar code reader:** Build-in MACS<sup>®</sup> TubeSealer for easy welding off and barcode reader for faultless recording



# CentriCult™ Unit

## Cell processing and specific labeling of cells



### Features of the CentriCult Unit

- **Fully-automated cell processing**, magnetic labeling, washing, and cultivation
- Right temperature, pH and gas mix (i.e. air, CO<sub>2</sub>, N<sub>2</sub>) supports cultivation and **expansion of cells** (e.g. T cells, NK cells, HSCs, dendritic cells, MSCs, iPSCs, iPSC derivatives)
- **Integrated centrifugation with camera-controlled layer detection** allows for automated cell washing and buffer exchange
- **Automated cell labeling** with CliniMACS® Reagents for subsequent separation
- Closed connection and sterile welding to **External Culture Vessels (ECVs)** to expand the cultivation volume for scalable cell manufacturing



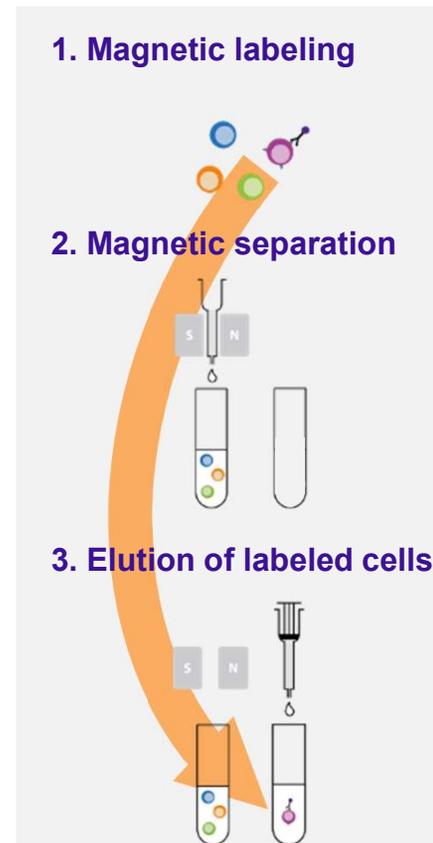
# CliniMACS® Separation Column

## Separating labeled and unlabeled cells

### Integrated cell enrichment or depletion step

- CliniMACS Separation Column provides **commercial-scale cell enrichment or depletion** by surface markers
- Facilitates to start complex procedures (e.g. manufacturing of CAR T cells) with well-defined cell population for robust and standardized process
- Separation takes place as a **closed, integrated step** in the CliniMACS Prodigy®

### Principle



# CliniMACS Prodigy® Tubing Set

## Sealed and protective environment for your cells



### Disposable Tubing Sets



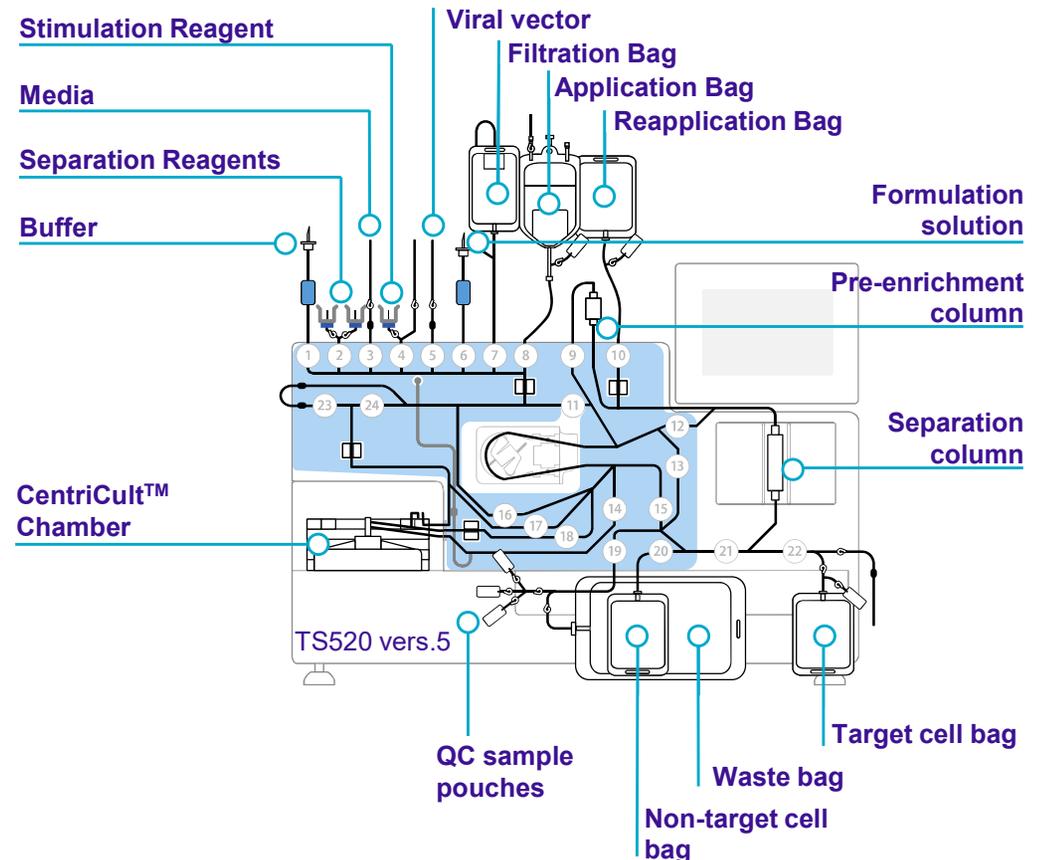
- **Single-use, closed environment**
- **GMP-compliant** cell processing
- **Multiple compartments** within one tubing set for cell washing, sample preparation, separation, genetic modification, cultivation, and formulation



- **Variety of validated tubing sets** support verified clinical applications



- **Range of accessories available** to customize the tubing set to support specific needs



# CliniMACS Prodigy® Tubing Set

## Maximum flexibility and safety by sterile welding



### Modular connectivity and flexible handling

- **Sterile welding** for adding or removing tubing compartments (e.g. external cultivation vessels, reagent bags, sample pouches)
- **Sterile input ports** for easy connection of starting material, reagents, media, and buffers
- **Integrated sampling pouches** easily removable from tubing set for in-process control and quality control (IPC/QC)



*Integrated MACS® TubeSealer*



*Tubing set compatible for sterile welding*

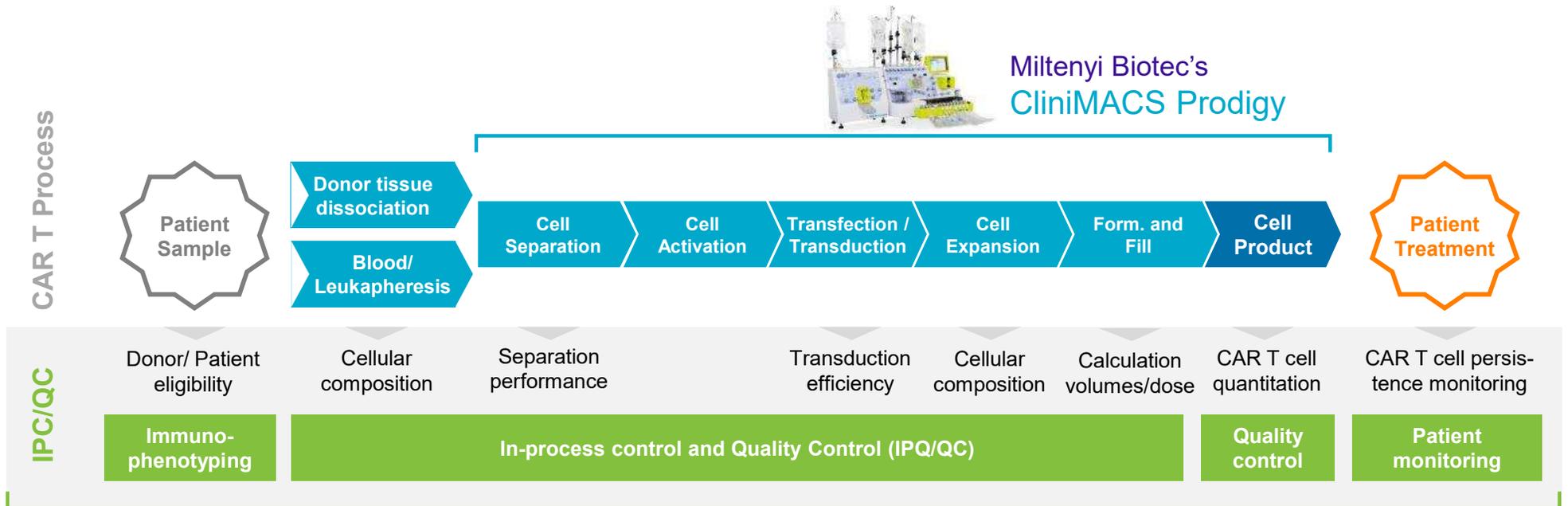


*Easily removable sampling pouches by sealing off from tubing set*



# CliniMACS Prodigy<sup>®</sup> linked to the MACSQuant<sup>®</sup>

## Continuous in-process control and quality control



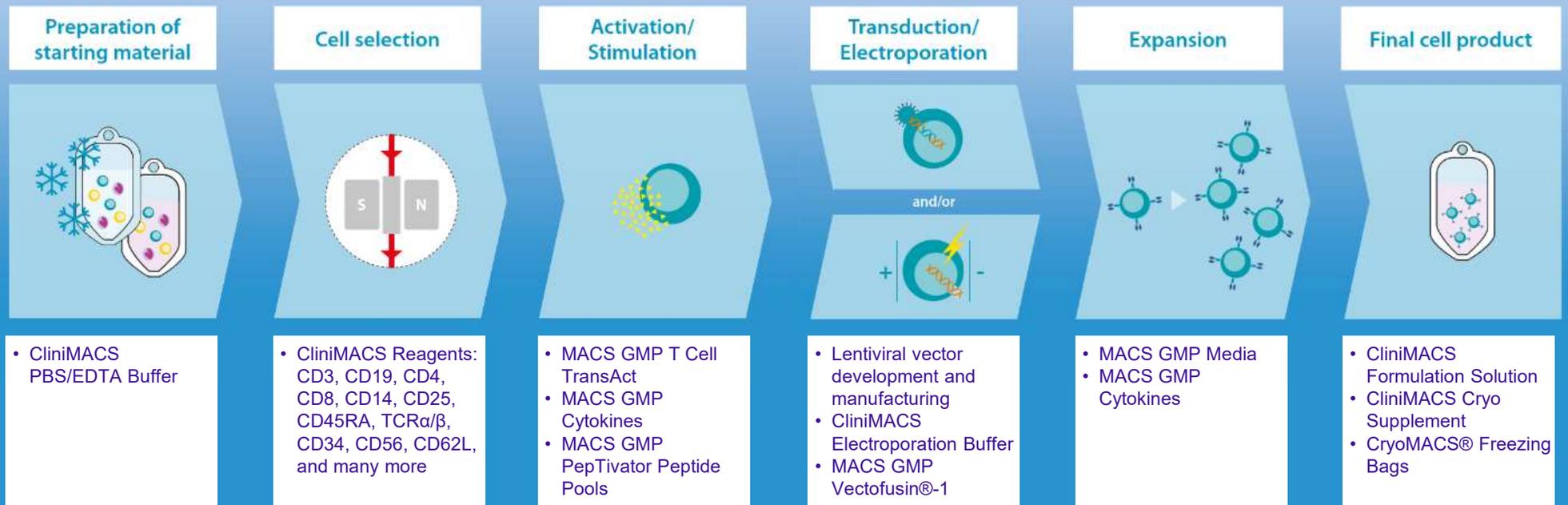
Miltenyi Biotec's CliniMACS Prodigy



Miltenyi Biotec's MACSQuant<sup>®</sup> Analyzer

# A full manufacturing solution

## MACS® GMP products



- A full end-to-end approach for cell manufacturing
- The choice of a one-stop audit solution
- Proven performance and validated in endless manufacturing processes

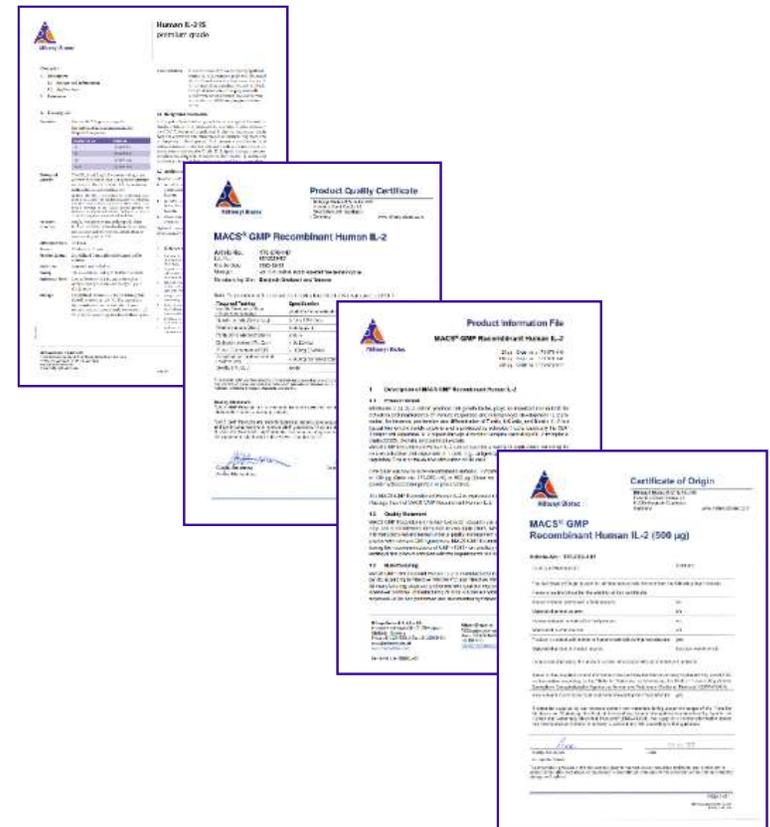
# MACS® GMP products

## Regulatory support



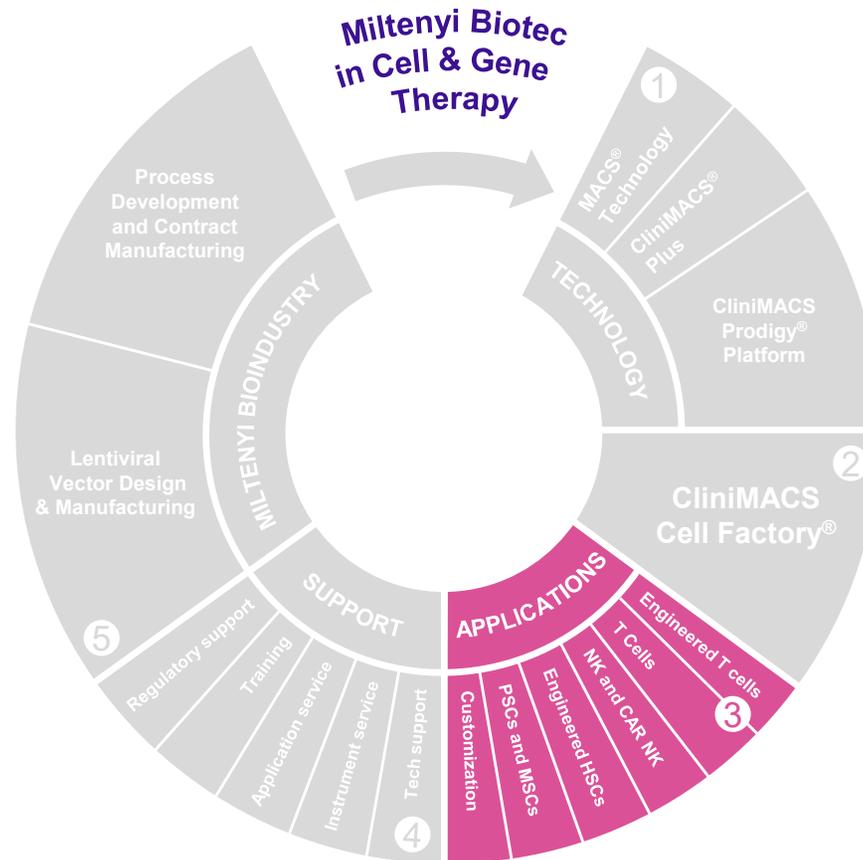
### Product-specific documentation

- **Package Insert**
- **Batch-specific Product Quality Certificate (PQC)**  
use by date, identity, biological activity (lot-specific IU/mg), endotoxin content and sterility test according to Ph. Eur., highly accurate analytical tests to determine purity and potential contaminants
- **Product Information File (PIF)**
- **Masterfile in USA** for selected products
- **Certificate of Origin (CoO)/TSE (transmissible spongiform encephalopathies)**



Most raw materials are part of the  
MACS GMP Portfolio

# Your partner in Cell & Gene Therapy Applications



# CliniMACS Prodigy® for different cells

## Clinically proven applications for various cell types



Gene-engineered T cells

Virus-specific T cells

Regulatory T cells

Tumor reactive T cells

NK and gene-engineered NK cells

Dendritic cells

Adherent iPSC and MSC

Gene-engineered HSCs

Graft engineering

# A portfolio of different applications

## Broad range of CE- and GMP-verified processes



### 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 $\gamma$ ) Enrichment

### NK cells

- CE** LP-3-56 Separation
- GMP** PD-56 Engineering
- GMP** NK Cell Transduction (LP-3-56 + PD-56)

### Graft Engineering

- CE** LP-34 Enrichment
- CE** LP-TCRab-19 Depletion
- CE** LP-TCRab-19-45RA Depletion

### Engineered HSCs

- CE** LP-34 Enrichment
- GMP** HSC Engineering

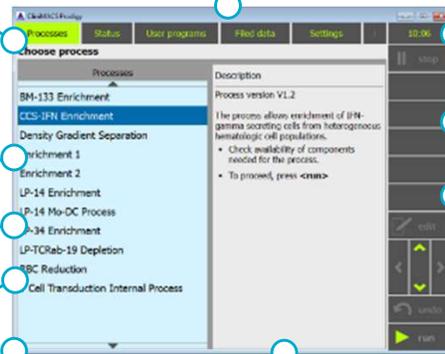
### PSCs and MSCs

- GMP** Adherent Cell Culture

### Monocytes / DCs

- CE** LP-14 Enrichment
- GMP** LP-14 Mo-DC Process
- GMP** Blood DC Enrichment and Culture (process combination)

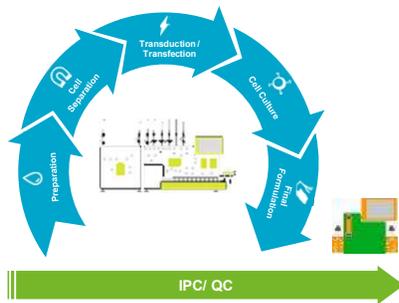
### Customized Applications



# Pre-installed, ready-to-go cell manufacturing protocols for a variety of cell types



## Selection of different workflows



- Engineered T cells incl. CAR T cells
- T cell Transduction – Large-scale
- T cells (Tregs)
- NK cells and CAR NK (NKCT)
- Engineered HSCs (HSCE)
- PSCs and MSCs (ACC)
- Customized applications

## Benefits



- ✓ **Complete and proven end-to-end workflow** to manufacture reliable cell products
- ✓ Applications designed to **increase process robustness** and **reduce regulatory requirements**
- ✓ **Highly skilled technical support** and long-lasting experience
- ✓ Process development services available via our CDMO arm, Miltenyi Bioindustry
- ✓ **Includes GMP-compliant reagents ideal for clinical research workflows**

# Application: CAR T cells

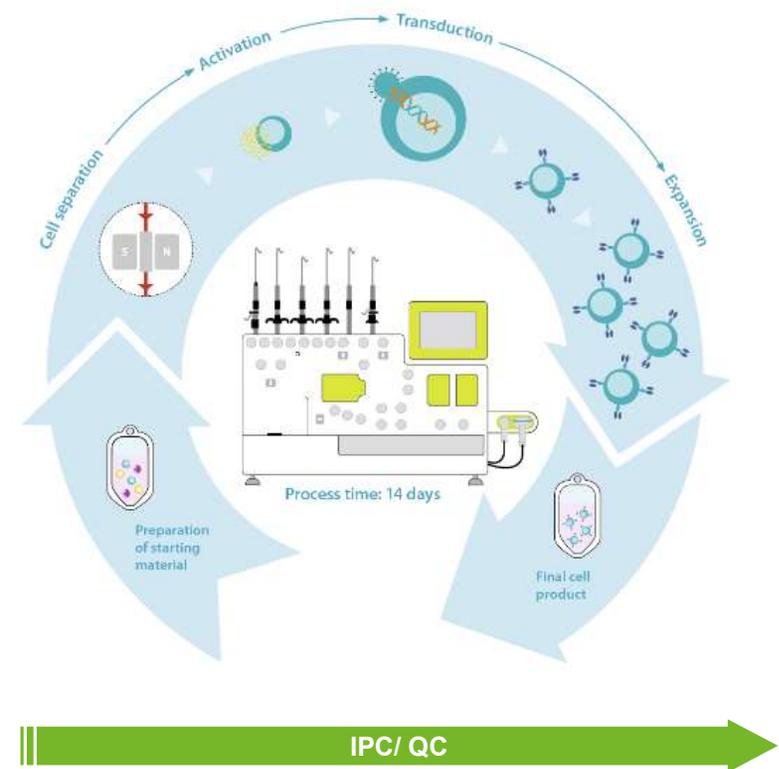
## T Cell Transduction

### Key feature

Automated manufacturing of CAR T cells

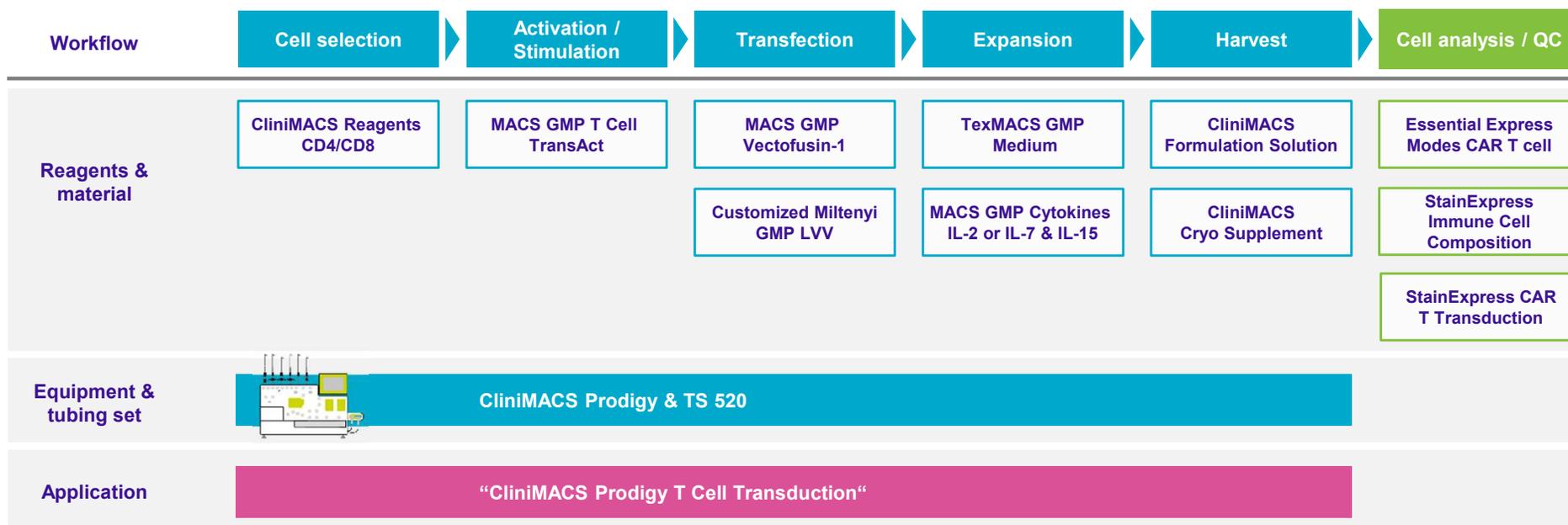
### Benefits

- Automated red blood cell reduction is optional, but this allows the use of **heterogenous starting materials** (e.g. whole blood)
- **Two T cell enrichment strategies** (CD62L or combined CD4/CD8) available
- **Different entry points** increase the versatility of the process
- **Customizable culture conditions** due to programmable activity matrix
- **Retroviral and lentiviral transduction strategies** supported



# Workflow

## T Cell Transduction



**Manufacturing time** 8–14 days

**Final cell number** about  $5 \times 10^9$  T cells  
about  $2 \times 10^9$  CAR<sup>+</sup> T cells (dependent on the vector)

# Application: CAR T cells and others

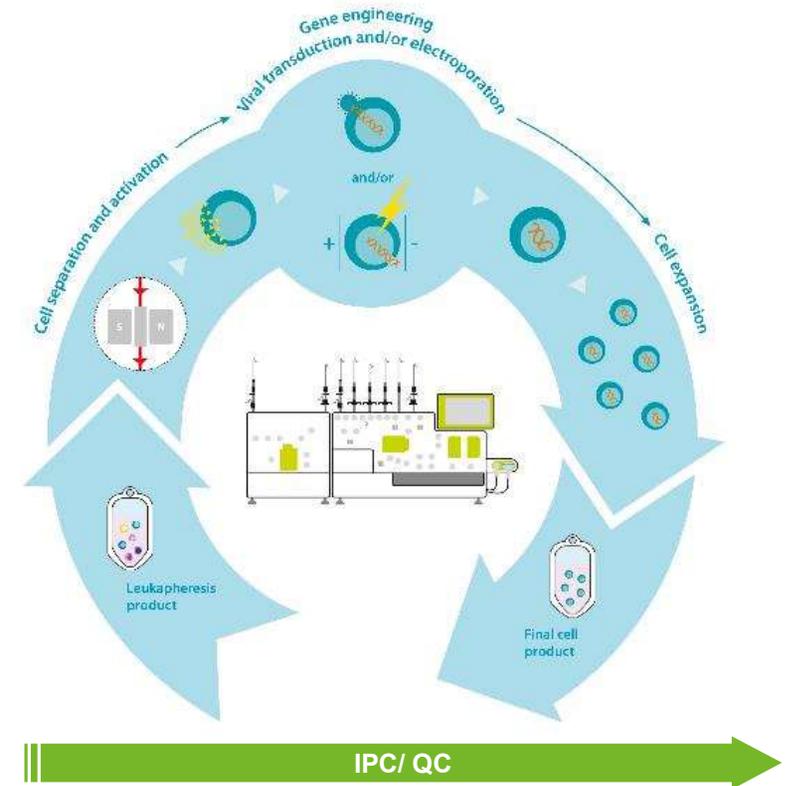
## T Cell Engineering

### Key feature

Automated manufacturing of engineered T cells by the flexible combination of transfection and/or viral transduction

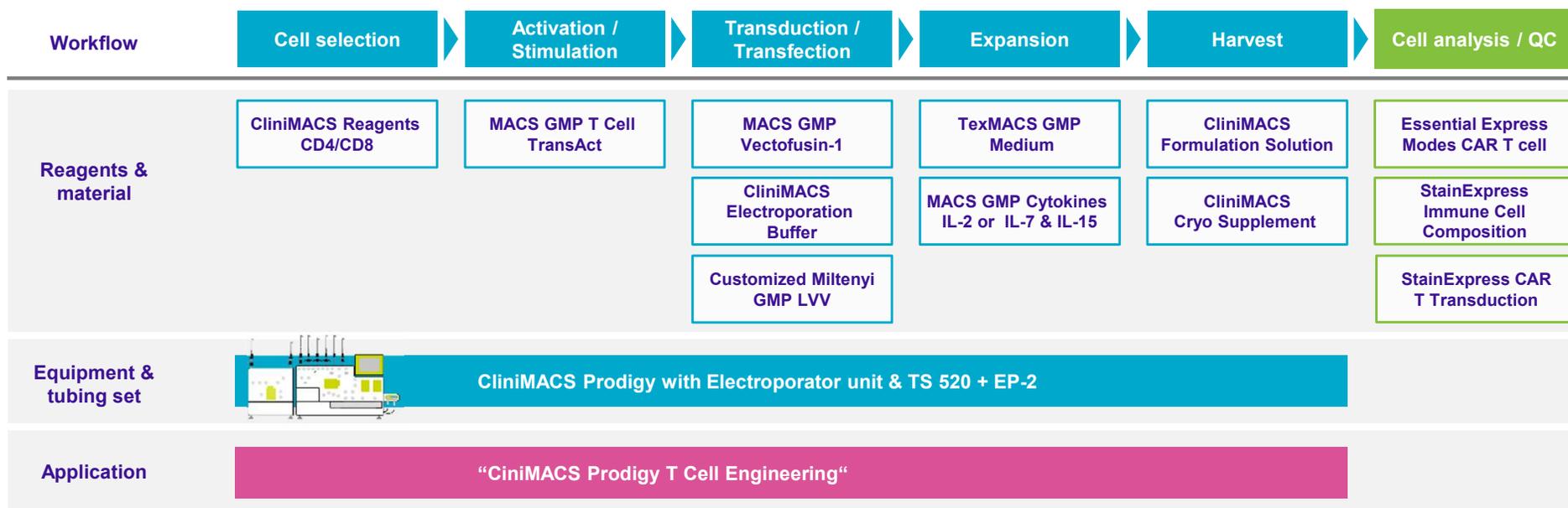
### Benefits

- **Combination** of electroporation with viral transduction
- **Automated mixing** of cells and nucleic acid directly before electroporation to avoid nucleic acid degradation
- **Fully adjustable electroporation parameters**
- **Quick electroporation and direct transfer** back into cultivation
- **Easy start-up** in small-scale and scale-up



# Workflow

## T Cell Engineering



**Manufacturing time** 10–14 days

**Final cell number** about  $2 \times 10^9$  T cells (dependent on transfection efficiency)

# Application: Regulatory T cells

## Treg LP-25 Pre-Enrichment

### Key feature

Combined **magnetic pre-enrichment** of fluorescent-labelled CD25<sup>+</sup> cells, and their **ultra-pure cell sorting** with MACSQuant<sup>®</sup> Tyto<sup>®</sup>

### Benefits

- **Easy, fast and ultra-pure** flow sorting of small cell populations such as naive Treg cells
- **Robust and clinically proven workflow**

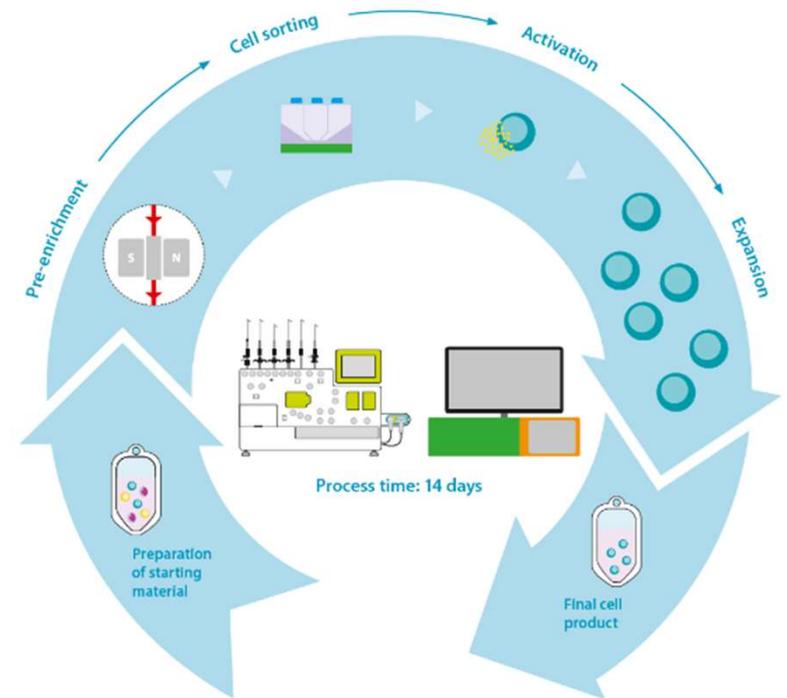


Pre-enrichment

CD25<sup>+</sup> enriched and labeled cells

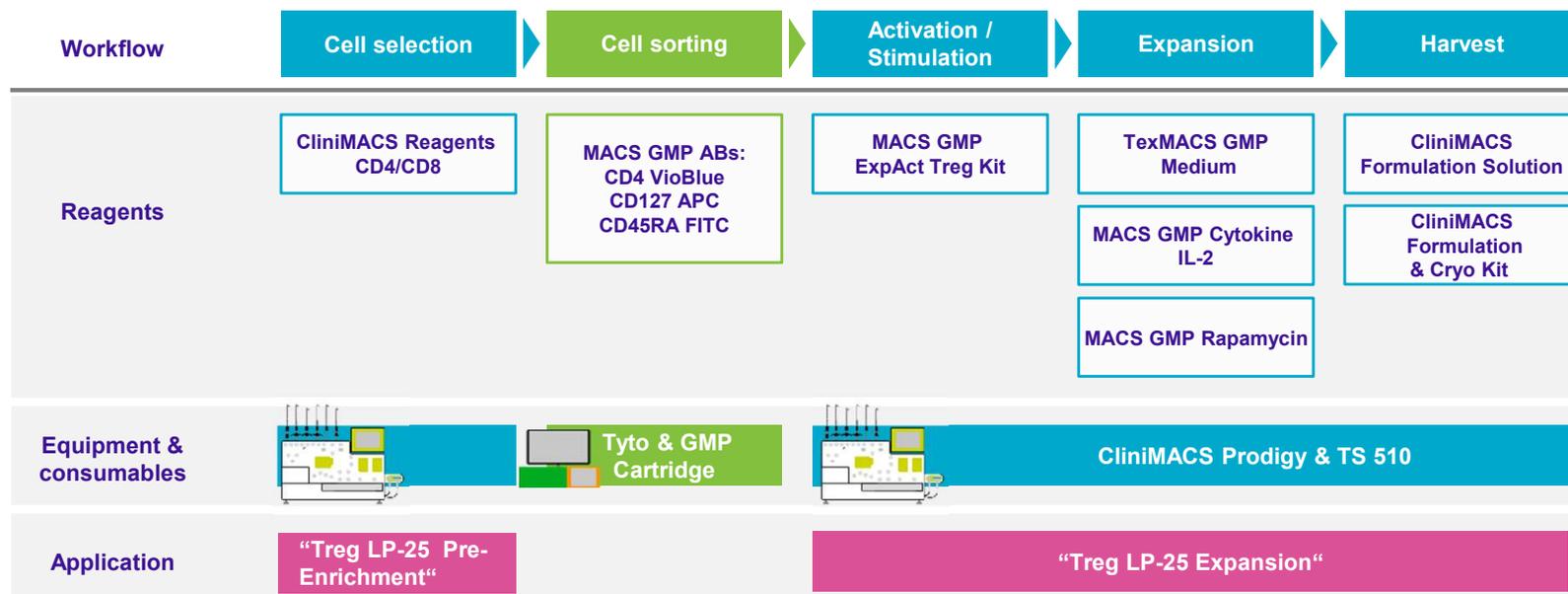


Cell sorting



# Workflow

## Treg LP-25 isolation & optional expansion with a CAP



<b>Hands-on-time</b>	1 h (for Treg cell sorting)
<b>Manufacturing time</b>	10 h isolation 12–36 days cell expansion
<b>Final cell number</b>	50–1000x cell expansion (donor-dependent)

# Application: NK cells

## CliniMACS Prodigy<sup>®</sup> CD3/CD56 System

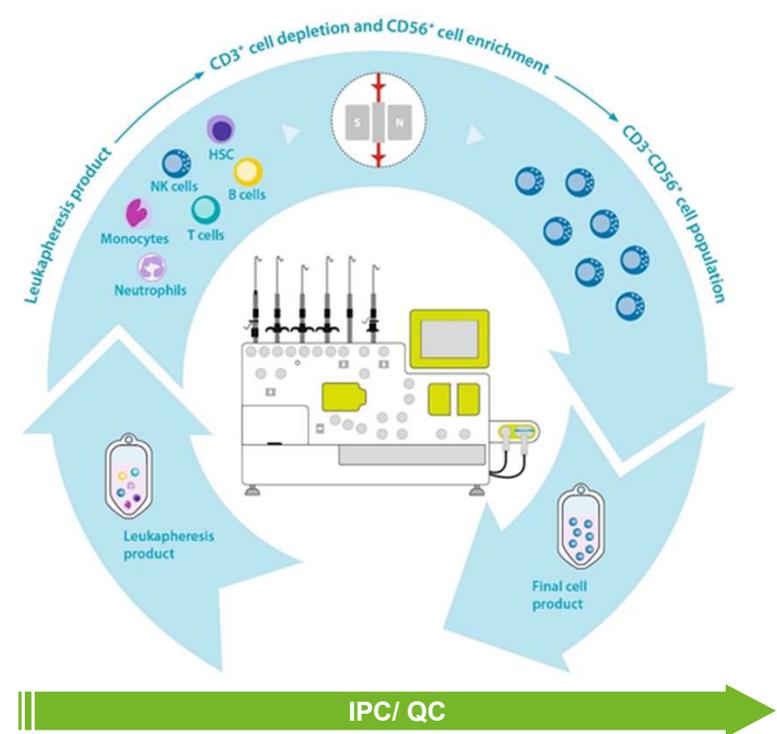


### Key features

**Enrichment of NK cells** via CD3 depletion or enrichment via a combined CD3 depletion/CD56 enrichment **for efficient T and B cell depletion**

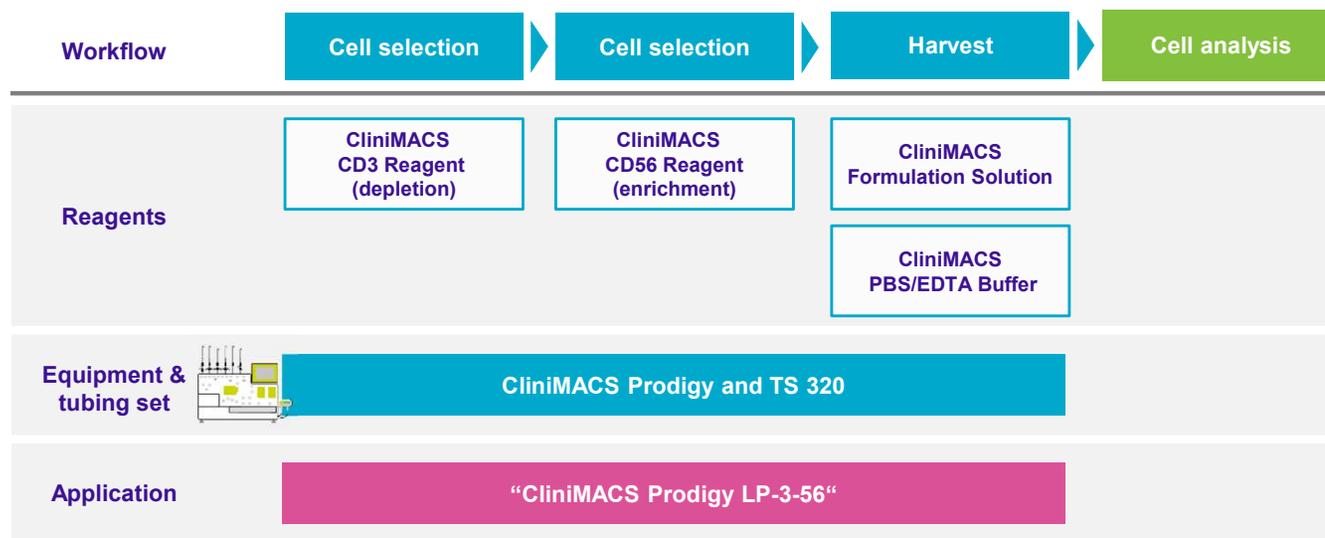
### Benefits

- Clinical-grade isolation of CD3-CD56<sup>+</sup> NK cells
- Only one tubing set for two selection steps required
- Fully automated operation of two selection steps
- Possibility to perform NKCT (PD-56) subsequently in case of interest in CAR NK cell manufacturing



# Workflow

## LP-3-56 workflow



<b>Hands-on-time</b>	about 1-2 hours
<b>Manufacturing time</b>	up to 10 hours
<b>Final cell number</b>	$4.5 \times 10^9$ total CD3-CD56 <sup>+</sup> NK cells

# Application: Engineered HSCs

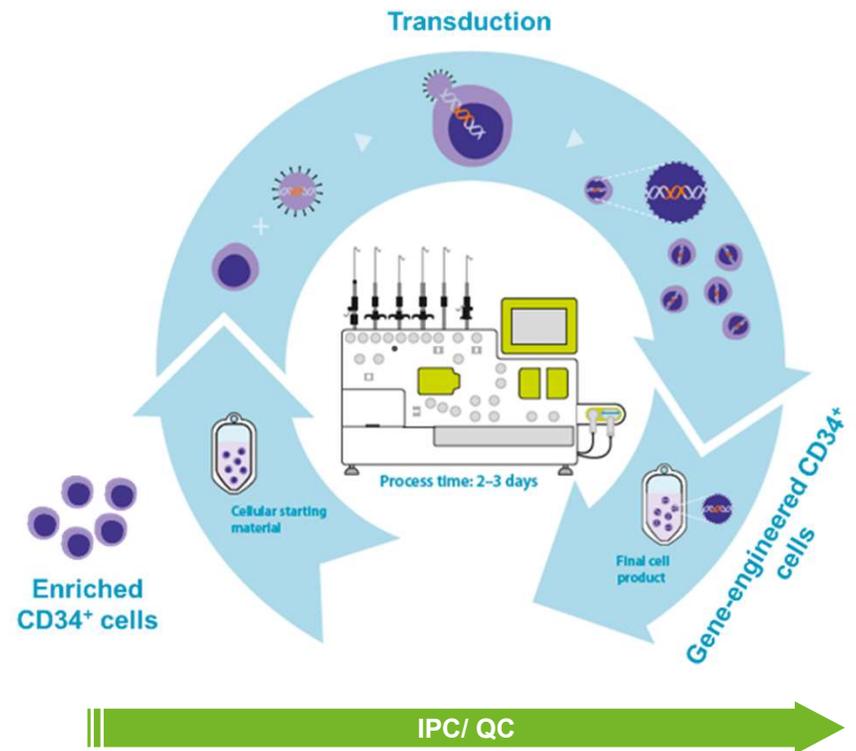
## Hematopoietic Stem Cell Engineering

### Key features

Automated manufacturing of gene-engineered hematopoietic stem cells (HSCs) by **viral transduction of human CD34<sup>+</sup> cells**

### Benefits

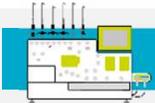
- **Automated** process for standardized steps and final cell products
- **Robust** performance reduces impact of donor variations on final cell quality
- **Flexible** software for easy conversion of your manual transduction process of human CD34<sup>+</sup> cells
- **Functionally closed system** reducing cleanroom requirements as well as increasing product and operator safety



# Workflow

## Hematopoietic Stem Cell Engineering



Workflow	Expansion	Transduction	Harvest	Cell analysis / QC	
Reagents & material	<p>HSC-Brew GMP Medium, human</p> <p>MACS GMP Cytokines SCF, TPO, Flt3-Ligand, IL-3</p>	<p>MACS GMP Vectofusin-1</p> <p>Customized Miltenyi GMP LVV</p>	<p>Physiologic NaCl with 0.5% HSA</p>	<p>StemMACS HSC-CFU Media &amp; StemMACS HSC-CFU Assay Kit, human</p> <p>CD34/CD133 Enumeration Kit</p>	<p>(REAfinity™) Antibodies, Viability™ Fixable Dyes, 7-AAD Staining Solution</p> <p>MACS COPYcheck Kit, human (applicable for Lentigen vectors)</p>
Equipment & tubing set	 <p>CliniMACS Prodigy &amp; TS 520</p>				
Application	<p>“CliniMACS Prodigy HSC Engineering“</p>				



**Hands-on-time** about 2 hours (incl. material preparation)

**Manufacturing time** 2–3 days

**High cell viability** > 90%

# Application: Adherent Cell Culture

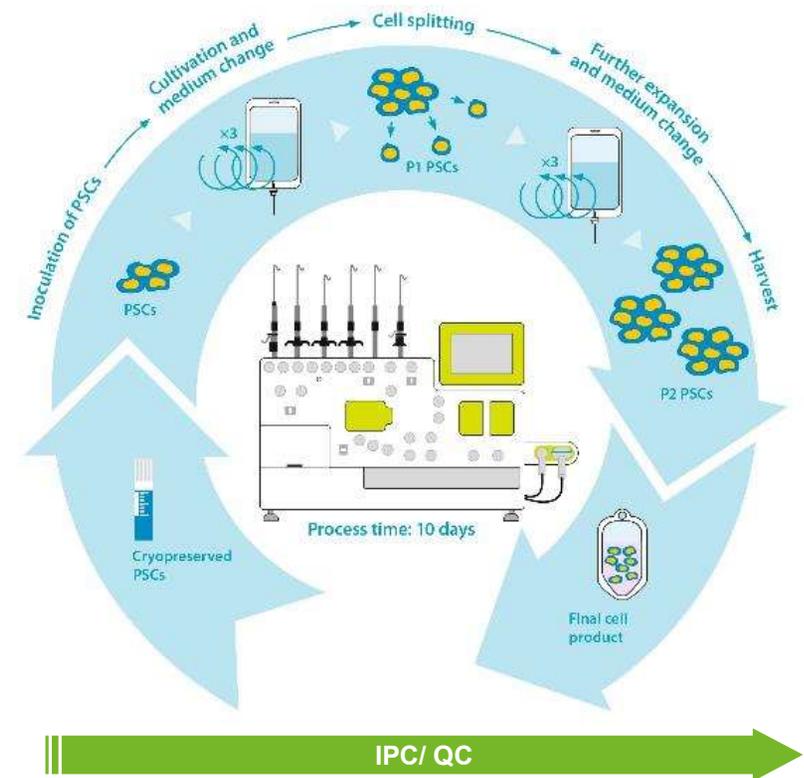
## Automated PSC expansion & differentiation

### Key features

Automated **expansion and differentiation** of PSCs in a closed and scalable system

### Benefits

- **Flexible modules** (e.g. coating, inoculation, media change, harvest) support cultivation of various adherent cell types
- **Scalable cell culture** with external culture vessels
- **Compatible products** including iPS-Brew GMP Media, MACS® GMP cytokines, and QC reagents
- Supports **GMP-compliant** PSC expansion, and PSC differentiation to midbrain dopaminergic (mDA) progenitors and cardiomyocytes



# Workflow

## Automated PSC expansion



Workflow	Expansion	Harvest	Cell analysis / QC
Reagents	iPS-Brew GMP Medium	CryoMACS Freezing Bags	Flow panel: expression of pluripotency-associated markers
	MACS GMP TGF-β1		StemMACS Trilineage Differentiation Kit, human
Equipment & tubing set			
Application	CliniMACS Prodigy Adherent Cell Culture		



- Hands-on-time**      about 5 hours
- Manufacturing time**      10 days relates to two cell passages
- High cell viability**       $\sim 5 \times 10^8$  cells (start with  $1 \times 10^6$  PSCs)

# Workflow

## Automated PSC differentiation to mDA progenitors



<b>Workflow</b>	mDA progenitor differentiation	Harvest	Cell analysis
<b>Reagents</b>	MACS GMP Recombinant Human SHH	CryoMACS Freezing Bags	PSC-mDA Neuron Phenotyping Kit, human
<b>Equipment &amp; tubing set</b>	 CliniMACS Prodigy & TS 730		
<b>Application</b>	CliniMACS Prodigy Adherent Cell Culture		



<b>Hands-on-time</b>	about 12 hours
<b>Manufacturing time</b>	21 days (5 days pre-expansion & 16 days differentiation)
<b>Final cell number</b>	~ $3.8 \times 10^9$ cells (start with $10^6$ PSCs)

# Workflow

## Automated PSC differentiation to cardiomyocytes



Workflow	Cardiomyocyte differentiation	Harvest	Cell analysis
Reagents	StemMACS CardioDiff Kit XF, human (RUO)	CryoMACS Freezing Bags	Flow panel for characterization of PSC-derived cardiomyocyte
Equipment & tubing set	 CliniMACS Prodigy & TS 730		
Application	CliniMACS Prodigy Adherent Cell Culture		



<b>Hands-on-time</b>	about 10 hours
<b>Manufacturing time</b>	8 days
<b>Final cell number</b>	up to $2.9 \times 10^8$ cells in a CellSTACK 1-layer (start with $\sim 1.6 \times 10^8$ PSCs)

# Application: Adherent Cell Culture

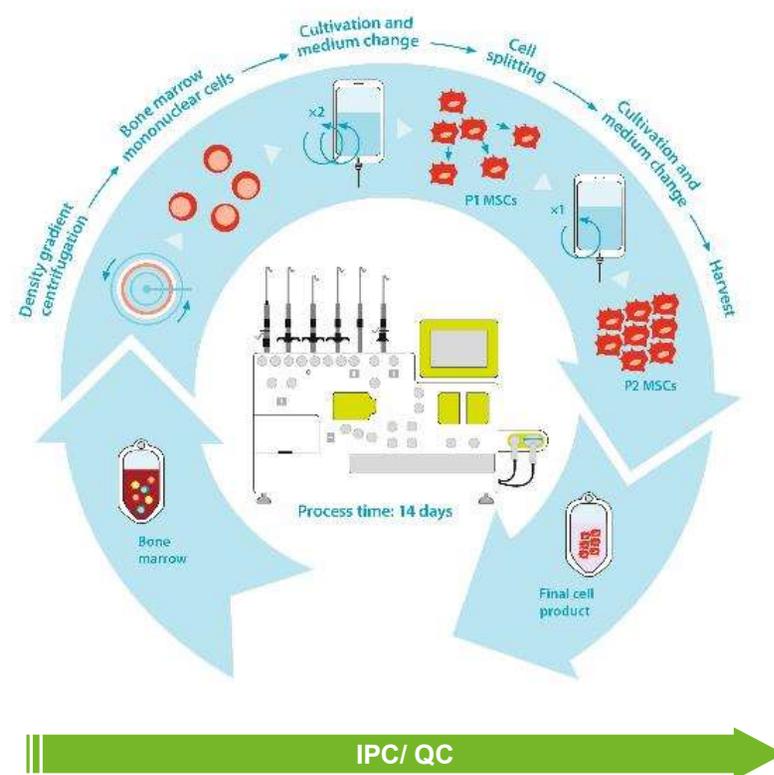
## Automated MSC expansion

### Key features

Automated GMP-compliant **MSC expansion** in a closed and scalable system

### Benefits

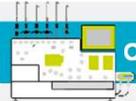
- **Flexible starting materials** from bone marrow, umbilical cord, to adipose tissues
- Flexible modules that include specifically designed density gradient centrifugation, inoculation, media exchange, and harvest enable **ready-to-use MSC manufacturing workflow**
- **Scalable cell culture** with external culture vessels
- **Compatible products** including MSC-Brew GMP Medium, MSC Phenotyping Kit, MSC differentiation media
- **Resulting MSCs meet ISCT criteria** (i.e. high expression of MSC positive markers and lack of non-MSC markers, can differentiate into osteoblasts, adipocytes, and chondrocytes)



# Workflow

## Automated MSC expansion



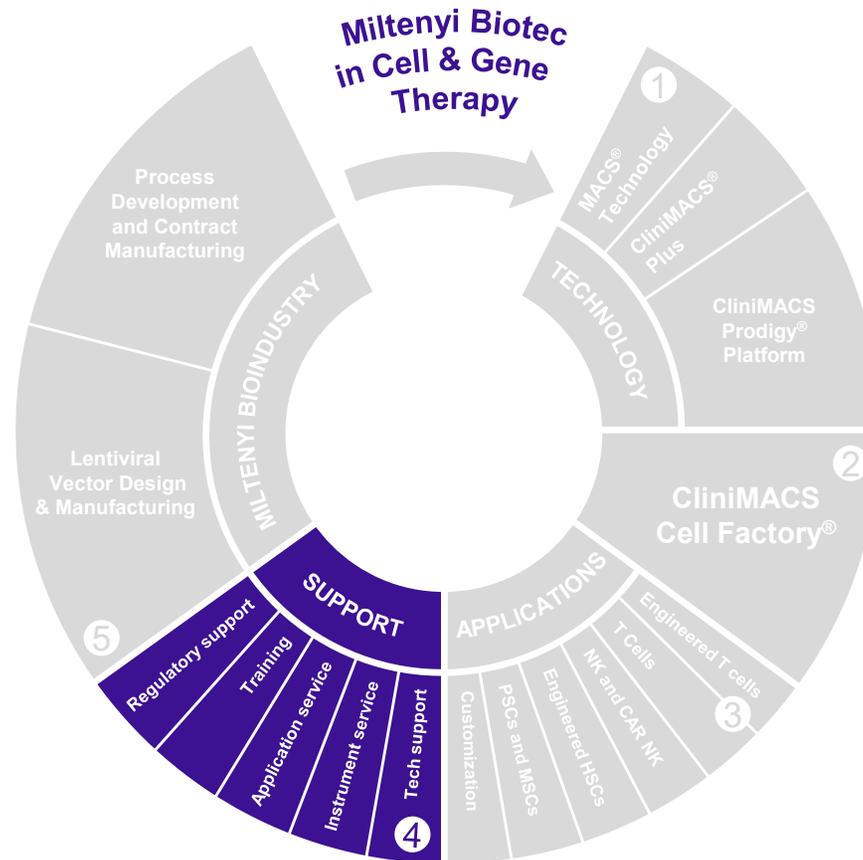
Workflow	Expansion	Harvest	Cell analysis
Reagents	MSC-Brew GMP Medium	CryoMACS Freezing Bags	MSC Phenotyping Kit, human MSC Suppression Inspector, human StemMACS AdipoDiff/ OsteoDiff/ ChondroDiff Media, human
Equipment & tubing set	 CliniMACS Prodigy & TS 730		
Application	CliniMACS Prodigy Adherent Cell Culture		



**Hands-on-time**                      about 3 hours  
**Manufacturing time**                14 days relates to two cell passages  
**Final cell number**                     $\sim 4 \times 10^8$  cells (start with 30–100 mL human bone marrow sample)

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**Thank you for your attention**

