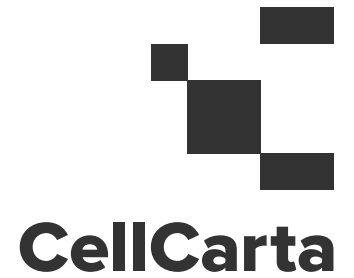
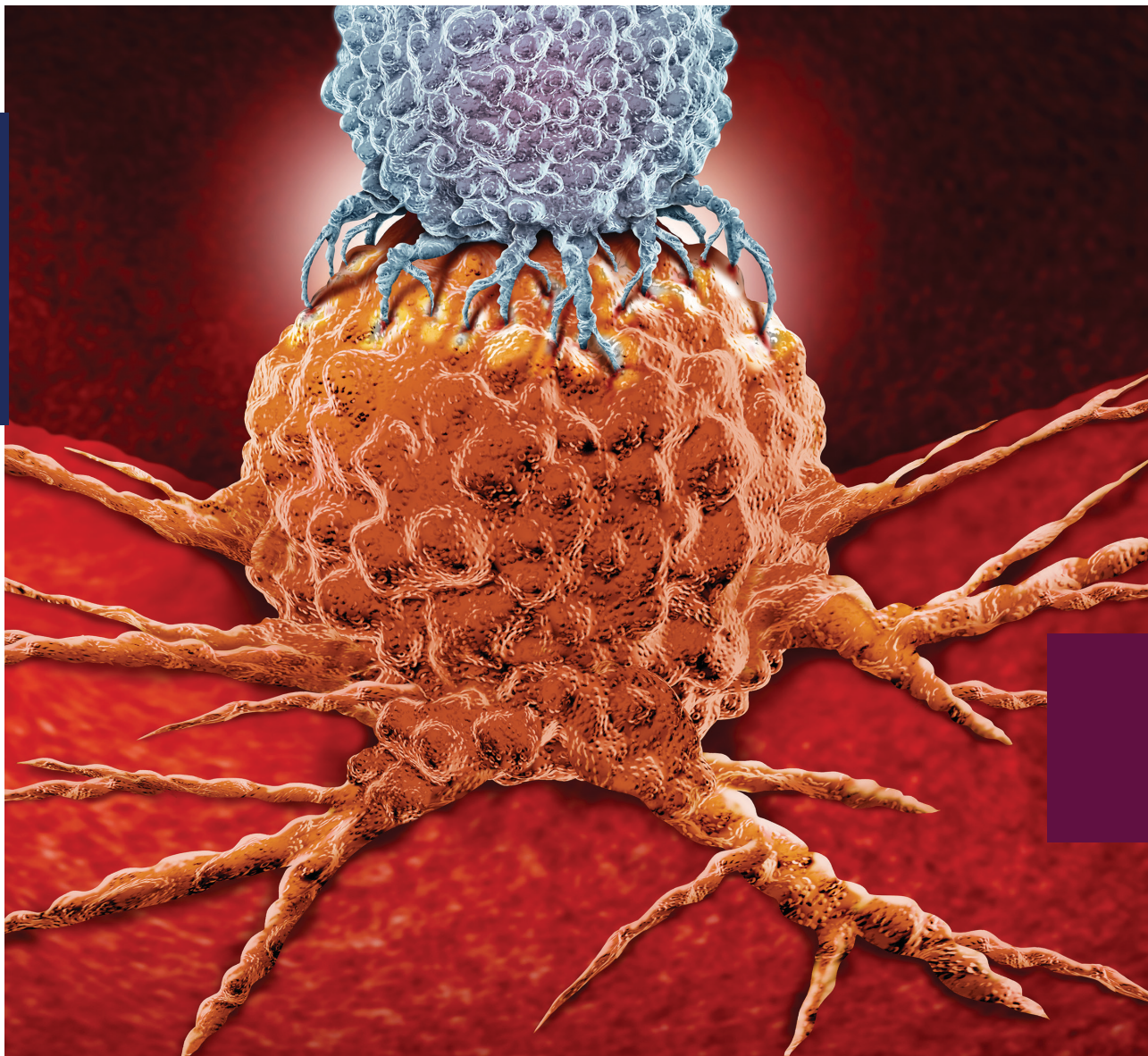


Cell Therapy



Accelerate the Development
of Your Cell Therapy Program



Addressing the Challenges of Cell Therapy

Cell therapy has revolutionized treatment of some hematological malignancies, yet the rapid and ongoing development of the technologies introduces new challenges during early development and clinical testing. Cell therapies covers a diverse set of strategies, including CAR-T cell therapy and tumor-infiltrating lymphocytes (TIL) therapy, both FDA-approved, as well as engineered T-cell receptor (TCR) therapy, and other CAR therapies (e.g. CAR-NK, CAR-NKT, CAR-M).

To navigate the complex and evolving therapeutic landscape, a strong scientific partner at the forefront of technical innovation will be a key component of success.

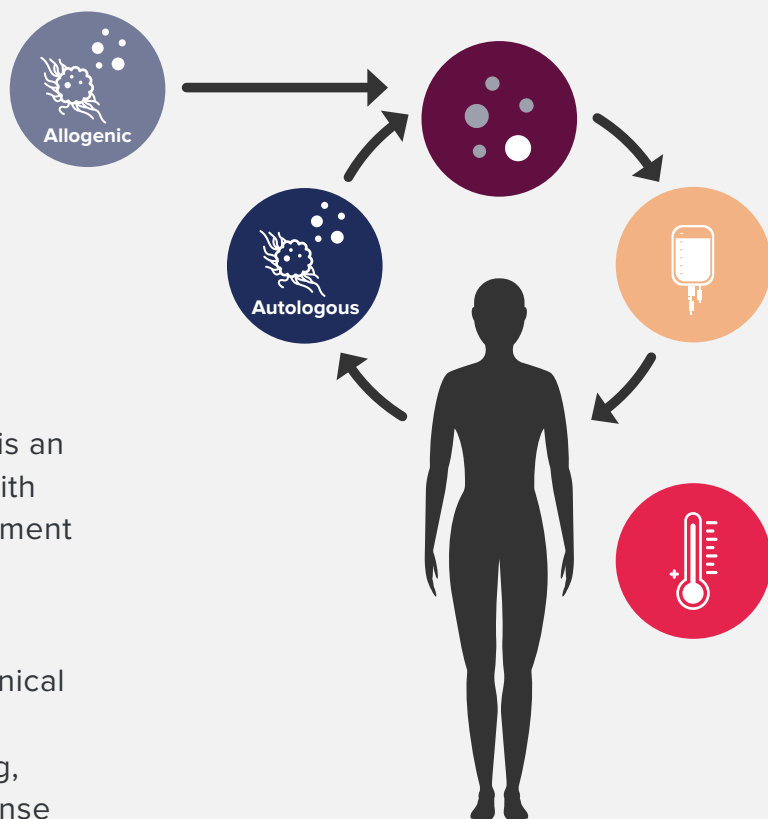
At CellCarta, we collaborate closely with you and provide critical biomarker support for your studies, anticipating clinical testing challenges and providing a quick turnaround time essential for decision making.

Our complete portfolio of cell therapy services includes customized biomarker solutions to propel your program forward with high quality data.

Providing a Strategic Advantage at Every Step with Our Cross-Platform Expertise

Your cell therapy is unique, requiring customized assays designed to address specific biomarker hypotheses. CellCarta is an organization driven by biomarker experts with +20 years of experience in custom development and analysis.

Benefit from our comprehensive range of platform technologies during all steps of clinical development, from product development, patient selection and pre-treatment profiling, as well as safety assessment, patient response and drug product monitoring post infusion.



Enhancing Product Development

Get the crucial data you need to make informed decisions concerning your cell therapy process prior to clinical testing.

Our genomics-based solutions, such as digital PCR (dPCR), quantitative PCR (qPCR) allow for the determination of **vector copy number (VCN)** for pharmacokinetics (PK) analysis and monitoring of **replication competent retroviruses (RCR) or lentiviruses (RCL)** for safety assessments.

To determine **absolute cell count**, TBNK by flow cytometry is performed using Trucount™ tubes. At the cellular level, flow cytometry can

also be used to provide **cellular phenotyping** of the engineered cells, and assess the expression levels of CAR constructs, immune checkpoints, cellular armoring targets, as well as activation and exhaustion markers.

To understand how cellular expansion and function of the drug product can be influenced by the **cellular and clonal composition of the cell therapy product**, we offer RNA sequencing (RNAseq) at the single-cell level using CITE-seq.

Improving Patient Selection

Patient stratification and pre-treatment profiling are not only important for verifying the therapeutic target expression, but also key in assessing efficacy of treatment.

During patient selection and pre-treatment profiling, the **abundance, distribution, and localization of antigens of interest in tissues or plasma samples** can be explored for key tumor targets. For hematological malignancies, key biomarkers such as CD19, CD20, and BCMA are investigated using single or multiplex IHC. For solid tumors, known biomarkers such as HER2, NY-ESO-1, and MAGE-A4 are quantified using qPCR and mass spectrometry.

For targets that are based on TCR antigen recognition, **HLA typing** is performed using next-generation sequencing (NGS) to identify patients with correct haplotypes.

Profiling patients prior to treatment by measuring **lymphodepletion (TBNK), immune exhaustion, tumor mutational burden (TMB), microsatellite instabilities (MSI)**, and **presence of bridging therapy** (i.e. rituximab) are all critical to understanding treatment efficacy.

Evaluating Patient Treatment

Measuring the presence of RCR/RCL in patients following treatment is a key requirement for long-term monitoring of subjects. In addition, all types of cytokine derived toxicities relating to cell therapy **(CRS, ICANS, MAS)** can be evaluated using our various immunoassays platforms (MSD®, Olink®, ELISA). The immunogenicity of the drug product, investigating the cellular immune response triggered, also adds to the safety profiling of the treatment.

Once therapy is delivered, the drug product must be monitored. Its **pharmacokinetics** is evaluated by measuring VCN, the CAR construct is enumerated, and tissues are investigated in order to assess the infiltration of the tumor by the drug product.

Throughout the assessment, critical biomarkers are evaluated, and customized assays are also developed to keep track of the unique drug product.

These various biomarkers are used to accurately determine the patient's response to treatment over time. Immune profiling, including TBNK, along with characterization of the tumor environment, and monitoring of key soluble targets, all combine to provide insight into the therapy's efficacy and facilitate decision making for future clinical development stages.



Partner with CellCarta

to Accelerate the Development of Your Cell Therapy Program

- An established track record, with **over 150 completed and ongoing projects in cell therapy**
- Unparalleled scientific expertise with cross-platform capabilities - **your one-stop-shop for expertise in cell therapy**
- **Customized solutions.** Every project is unique, and we have the flexibility and agility to adapt to your needs
- **Highest standards in quality with CAP accreditations/CLIA certifications** and validation processes that meet the requirements for primary/secondary endpoints
- Providing full data insights with **AI-driven analysis and biological interpretation support**
- **Global presence** with eleven facilities located in Canada, USA, Belgium, Australia and China



	Assays	Technologies
Product Development	■ VCN measurement	■ dPCR
	■ RCR/RCL measurement	■ qPCR
	■ Assessment of biodistribution	■ dPCR
	■ Absolute cell count	■ flow cytometry*
	■ Cellular phenotyping	■ flow cytometry*
	■ Drug product characterization	■ CITE-Seq (single-cell analysis)
Patient Selection and Pre-Treatment Profiling	■ HLA typing	■ NGS
	■ Evaluating presence of drug target (e.g. BCMA)	■ IHC, qPCR, mass spectrometry
	■ Genomic profiling (key biomarkers, TMB, MSI)	■ qPCR, NGS, targeted RNAseq, FISH/ISH
	■ Lymphodepletion measurement (TBNK)	■ Flow cytometry*
	■ Immune exhaustion	■ Flow cytometry*
	■ Bridging therapy (e.g. rituximab)	■ ELISA
Patient Treatment: Patient Response and Drug Product Monitoring	Safety Assessment	
	■ RCR/RCL measurement	■ qPCR
	■ Immunogenicity (cellular immune response)	■ ELISpot, flow cytometry*
	■ Assessment of cytokine-driven toxicity (CRS, ICANS, MAS)	■ MSD®, Olink®, ELISA
	Patient Response and Drug Product Monitoring	
	■ TBNK	■ Flow cytometry*
	■ Immune profiling (cell surface, soluble markers)	■ Flow cytometry*, MSD®, Olink®, ELISA
	■ Assessment of tumour burden (e.g. ctDNA, CTCs)	■ IHC, qPCR, NGS, Rarecyte, mass spectrometry, MSD®, ELISA
	■ Pharmacokinetics – VCN	■ dPCR
	■ Cellular kinetics – CAR enumeration	■ Flow cytometry*
	■ CAR tumor infiltration	■ IHC/mIF

*Conventional flow cytometry, spectral flow cytometry, CYTOF

VCN: vector copy number, RCR: replication competent retroviruses, RCL: replication competent lentiviruses, dPCR: digital PCR, qPCR: quantitative PCR, CITE-Seq: cellular indexing of transcriptomes and epitopes sequencing, IHC: immunohistochemistry, FISH/ISH: fluorescent/ *in situ* hybridization, ELISA: enzyme-linked immunosorbent assay, NGS: next-generation sequencing, MSD®: MesoScale Discovery®, CRS : cytokine release syndrome, ICAN: immune effector cell-associated neurotoxicity syndrome, MAS: macrophage activation syndrome, TBNK: T cells-B cells-Natural Killer cells, CAR: chimeric antigen receptor, CTC: circulating tumor cells, ctDNA: circulating tumor DNA, mIF: multiplex immunofluorescence.

For more information on how CellCarta can partner with you, please contact us:

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