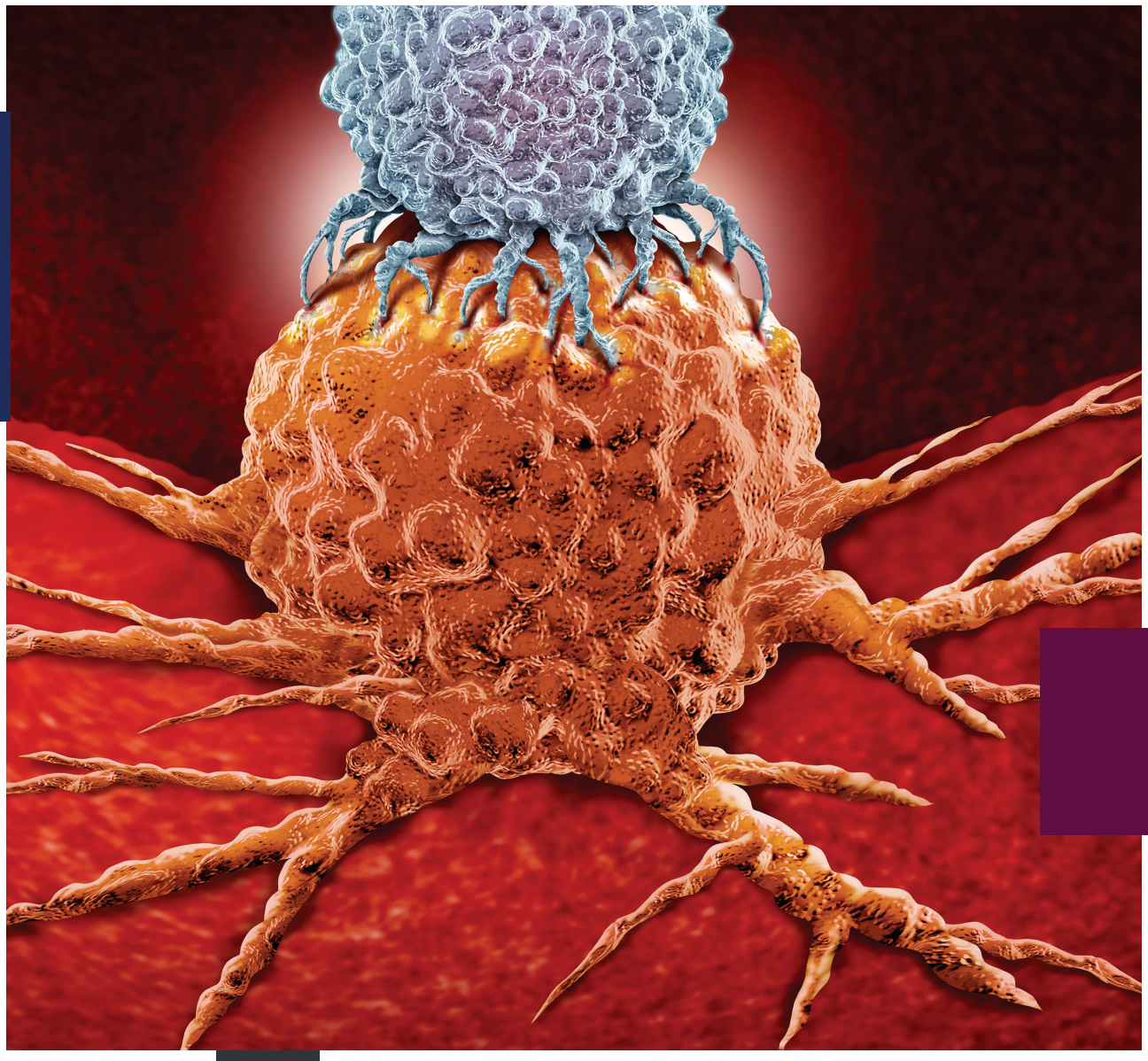
Cell Therapy

CellCarta

Accelerate the Development and Approval of Your Cell Therapy Program



Addressing the Challenges of Cell Therapy

Cell therapies have revolutionized treatment of some hematological malignancies, yet the newness of the technologies represents major challenges during their development and clinical testing. The diverse spectrum of cellular therapies includes 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 (γδT cells, natural killer cells, natural killer T cells, and myeloid cells). To navigate this complex and evolving field you need a scientific partner at the forefront of technologies.

At CellCarta, we collaborate closely with you and provide a critical edge to your studies, anticipating clinical testing challenges and providing a quick turnaround time essential to these studies.

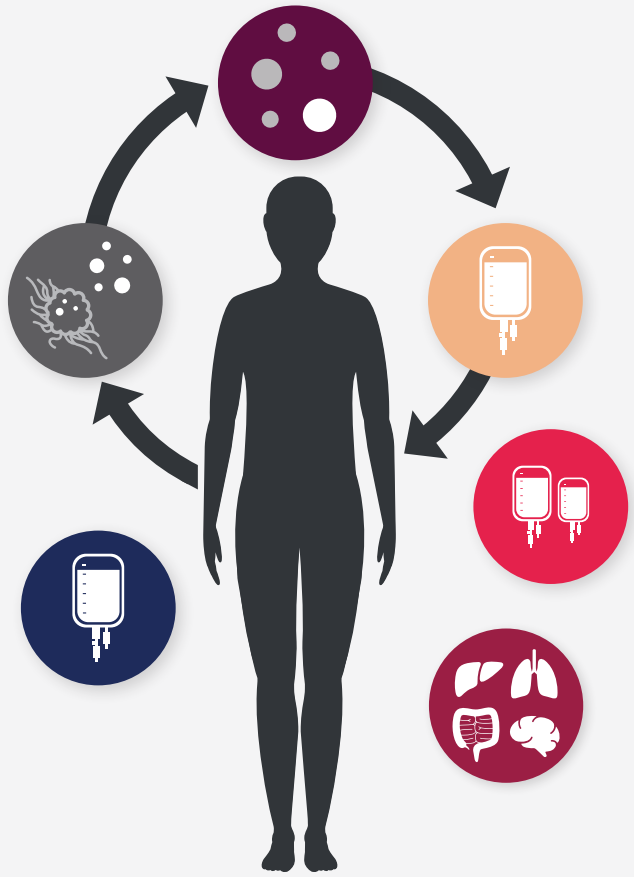
Our biomarker solutions and customized assays will give you with the insight you need to overcome cellular exhaustion and immunosuppressive tumor microenvironments (TME), enhance trafficking to solid tumors and much more.

QUALITY DATA TO MOVE YOUR CELL THERAPY PROGRAM FORWARD

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

Your cell therapy is unique so it makes sense that your bioanalysis would be customized. CellCarta is a biomarker expert with +20 years of proficiency in developing customer specific bioanalytical solutions.

Benefit from our comprehensive range of platform technologies during all steps of clinical development, from **product characterization, patient selection, to therapy and response monitoring, and toxicity assessment.**



Achieving the Next Level in Product Characterization

Our genomics-based solutions, such as digital PCR (dPCR), quantitative PCR (qPCR), targeted RNA profiling and next-generation sequencing (NGS) allow for the profiling of the engineered cells (CAR or TCR constructs). This includes the determination of **vector copy number (VCN) for pharmacokinetics (PK) analysis** and monitoring of replication competent r**etroviruses (RCR) or lentiviruses (RCL)** for safety.

At the cellular level, flow cytometry and CyTOF can be used to provide **surface profiling** of the engineered cells, and assess the expression levels of CAR constructs, immune checkpoints, as well as activation and exhaustion markers. Trucount™ tubes are used to determine **absolute cell count**.

Our immune monitoring tools can provide deeper assessment of cellular functionality with **antigen-specificity** and **cytokine expression** monitored through intra-cellular cytokine staining (ICS). **Multiplex cytokine response** can also be measured using the Meso Scale Discovery® (MSD®) and the ELISpot/FluoroSpot platforms.

As the cellular expansion and function of the overall treatment can be influenced by the **clonal composition of the product**, we offer RNA sequencing (RNAseq) at the single-cell level to investigate clonal kinetics.

Improving Patient Selection Using Complementary Platforms

Patient stratification is key in limiting toxicity and improving efficacy of treatment. CellCarta's **in-house team of board-certified pathologists** is a major asset to support patient stratification. The team provides their support to quantify new and established genetic biomarkers as well as key tumor targets in tissue samples.

Profiling the **general inflammatory state** of the patient as well as **lymphodepletion** status can support stratification and is achieved at the cellular level with inflammatory cytokine expression and TBNK enumeration.

Disease recurrence and development of cytokine release syndrome is correlated with tumor mutation burden (TMB) prior to treatment, which is why we offer **genetic biomarkers tracking** services, including mutational drivers.

During patient selection, the abundance, distribution, and localization of antigens of interest in tissues can be explored for **key tumor targets** such as MAGE4, NY-ESO-1, CD19, CD22, CD123, BCMA, using single or multiplex IHC. Some specific targets, such as **BCMA in multiple myeloma**, can be quantified in plasma samples as well as FFPE samples using mass spectrometry.

For patients **previously treated** prior to cellular therapy, CellCarta can monitor monoclonal antibody levels with ELISA.

Seizing the Power of Biomarker Analysis to Monitor Your Product and Its Therapeutic Response

Precision biomarkers to evaluate therapeutic response can be monitored with our wide variety of genomics, proteomics, histopathological, and immune monitoring techniques.

Once your therapy is delivered, its progression can be tracked over time **(cellular kinetics)** with various genomic services such as dPCR, qPCR, single-cell RNA sequencing, or with construct-specific antibodies by flow cytometry. The **presence of RCR/RCL** can be assessed in patients using qPCR assays while **PK analysis measuring VCN** is best performed using dPCR assays.

Additional immune profiling of engineered cells such as complete surface profiling and absolute cells counts can be performed in parallel with monitoring of key biomarkers.

Our team can provide **critical biomarker information** on T-cell activation and exhaustion, antigen presentation, tumor immune infiltration, as well as characterization of the TME using multiplex or singleplex IHC.

CellCarta can **monitor the patient's response to treatment** by measuring remaining tumor cells or tumor-specific targets. Some known targets can be measured by mass spectrometry (e.g. BCMA) or IHC with quantification supported by our **in-house team of pathologists**. The reconstitution of patient's immune system following treatment can be monitored by simply using a TBNK panel by flow cytometry.

Toxicity Assessment Simplified

For multiplexed, high-sensitivity, quantitative measurement of key inflammatory cytokines and chemokines, CellCarta offers the MSD® and the ELISA platforms. Our multiplex MSD® panels are readily available and aid in the screening of cytokine release syndrome.

Evaluating Combination Therapy

We monitor **critical biomarkers of efficacy** with high-throughput assays (MSD® and ELISA platforms) for sensitive and precise evaluation of combination therapies and their impact on overall treatment efficacy.

Partner with CellCarta
to Accelerate the Development and Approval 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

Clinical Development Steps	Platforms
Product Characterization	
Genomic profiling of target cells ■ PK analysis by VCN ■ Safety testing for RCR/RCL absence	■ dPCR and qPCR ■ Targeted RNA profiling and NGS ■ Single-cell RNA sequencing
Cellular profiling ■ Absolute cell count (Trucount™ tubes) ■ Off-the-shelf panels including key markers (activation/exhaustion, immune checkpoints) ■ Customized construct-specific panel ■ Functionality by ICS ■ *in vitro* antigen-specific functionality by cytokine response	■ Flow cytometry ■ CyTOF ■ MSD® ■ ELISpot/FluoroSpot
Patient Selection	
Characterization of patients' inflammatory state ■ Immune profiling – general panels ■ Lymphodepletion – TBNK panel ■ Cytokine profiling	■ Flow cytometry ■ MSD®
Tracking genetic biomarkers ■ Key patient mutations ■ Key tumor biomarkers ■ Microsatellite instability (MSI) ■ Tumor mutational burden (TMB)	■ qPCR ■ NGS (TSO500 panel by Illumina) ■ Targeted RNA profiling
Monitoring tumor targets ■ MAGE4, NY-ESO1, CD19, CD22, CD123, BCMA ■ soluble and FFPE BCMA	■ Immunohistochemistry (IHC) ■ Mass Spectrometry
Monitoring previous treatments ■ Detection of rituximab	■ ELISA
Monitoring Product and Therapeutic Response	
Tracking transgene or engineered cell ■ PK analysis by VCN ■ Safety testing for RCR/RCL absence	■ dPCR and qPCR ■ Targeted RNA profiling and NGS ■ Single-cell RNA sequencing
Immune profiling / cellular kinetics ■ Absolute cell counts (proliferation panels - TBNK) ■ Complete surface profiling - including immune checkpoints (PD-1, TIM-3, LAG-3), activation/exhaustion markers ■ ICS assays ■ Tissue biomarkers for T-cell activation/exhaustion, antigen presentation, immune infiltration, TME	■ Flow cytometry ■ IHC and multiplex IHC
Tracking remaining tumor cells or tumor-specific targets	■ IHC and multiplex IHC ■ Mass spectrometry (BCMA) ■ Flow cytometry
Toxicity Assessment	
Measurement of cytokine release syndrome	■ MSD® ■ ELISA
Combination Therapy	
PK of other biologics	■ MSD® ■ ELISA

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

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BR_CellTherapy_2022-03-08