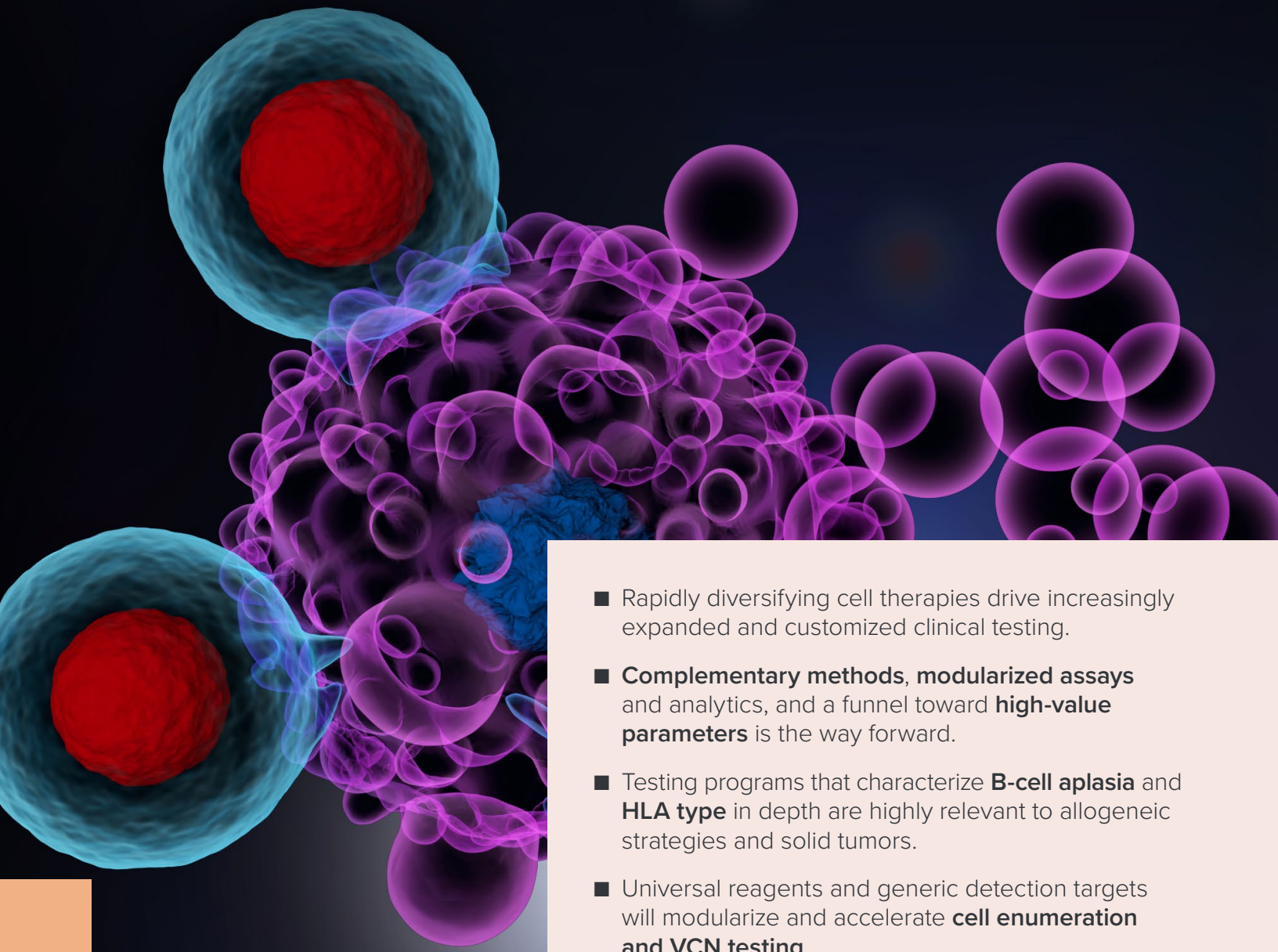
Cell therapy clinical testing

CellCarta

Trends in an ever-changing landscape



- Rapidly diversifying cell therapies drive increasingly expanded and customized clinical testing.
- **Complementary methods**, **modularized assays** and analytics, and a funnel toward **high-value parameters** is the way forward.
- Testing programs that characterize **B-cell aplasia** and **HLA type** in depth are highly relevant to allogeneic strategies and solid tumors.
- Universal reagents and generic detection targets will modularize and accelerate **cell enumeration and VCN testing**.
- Advanced analysis of **single-cell and cytokine profiling** data will unlock therapeutic efficacy and adverse events prediction.

TREND REPORT

Contents

The recent market approval of lifileucel (Amtagvi)[1] foretells exciting advances in cell therapy. As a tumor-infiltrating lymphocyte treatment for melanoma, lifileucel's approval is the first breakaway from CAR-based cell therapies and the first incursion into treating a non-hematological malignancy.

In the coming years, cell therapies will diversify in strategies and indications, raising new questions about their mechanisms and effects. As mature products progress to earlier treatment lines,[2] how will they interact with the immune system of less intensely treated patients? As a new generation of products that tap into a broader spectrum of targets, constructs, and cell types looms on the horizon, what must we know about them to ensure their safe and effective use?

A new era in cell therapy clinical testing

The clinical evaluation of future cell therapies must adapt to a more diverse and rapidly evolving array of products. For example, cell therapies for solid tumors favor private antigens that require assays customized for specific and proprietary targets. Allogeneic therapies have moved alternative agents like NK and γδT cells into the spotlight and their evaluation requires new biomarkers to characterize cell behavior and host responses. Lastly, increasingly complex and multimodal engineering constructs will swell testing programs with additional assays to probe each mechanism.

The numerous and diverse cellular products progressing to clinical stages will **intensify the burden on clinical testing programs to comprehensively characterize different cell therapy candidates**. Designing and validating the right array of assays will take time, even as pressure mounts to accelerate clinical development and the approval processes, shorten manufacturing timelines, and simplify logistics.

This insights report explores adaptations of clinical testing programs to the changing landscape of cell therapy. Five experts at CellCarta **describe broad-scale trends to accommodate diverse therapeutic approaches** and **examine five testing areas to highlight anticipated changes in assay development** as regulatory requirements and knowledge about disease and immunity evolve.

Tension between complexity and speed

The speed of today's ideation cycle for cell therapies vastly outstrips the pace of approval.[3] **The rapid diversification of targets, constructs, and cell types used in these new concepts necessitates a matching expansion in testing strategies**. Dr. Laïla-Aïcha Hanafi, Director of Scientific Lab Operations at CellCarta, points out, *"With diversified targets and multimodal constructs comes the need to create a suite of customized assays that test if all modes of action programmed into your construct produce the desired effect. This extensive characterization will be especially important for first-in-human trials."*

An expanded and customized characterization of cell therapy products to measure a broader range of parameters **conflicts with the push to accelerate cell therapy approvals and shorten their delivery time**.

Customized assays with robust, tractable, and affordable readouts take time to develop and validate. They must meet quality and reproducibility standards even with proprietary designs, budget limits, and pressure to progress to clinical trials as quickly as possible.

In addition, **the time window to execute clinical testing and return readouts will narrow**. *"Accelerated timelines in delivering cells to patients will squeeze turnaround times for clinical testing,"* explains Dr. Liesbet Vervoort, Group Leader in Program Management at CellCarta. *"We need to develop tests that can keep the pace."* Ultimately, testing methods will need to tackle complex clinical objectives with streamlined sample management, fast turnaround, and cost efficiency.

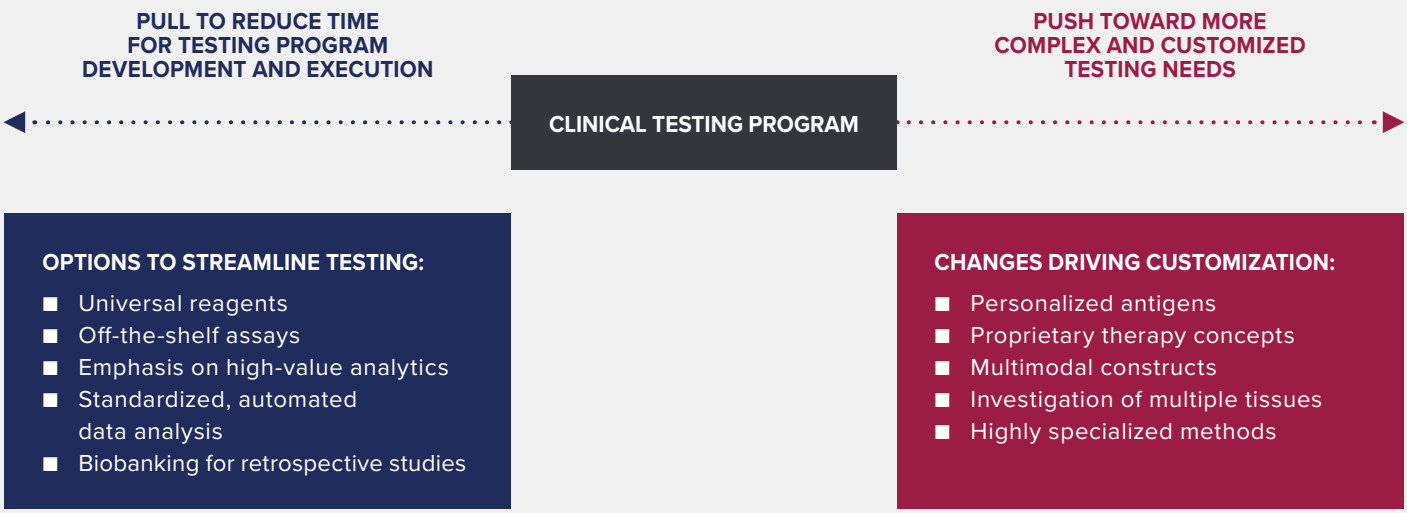


Figure 1: The variety of cell therapy concepts conflicts with the urgency to accelerate their development and approval. While pressure mounts to reach clinical proof of concept and regulatory approval for cell therapies, increasingly complex and customized testing needs lengthen the time to design, validate, and deploy (from sample management to data analysis) appropriate clinical testing programs.

Merging novelty and efficiency

Multimodal analytics in early-phase clinical evaluation with a mechanism to select high-value parameters and streamline testing in later phases balances complex characterization needs with the accelerated pace of cell therapy development.

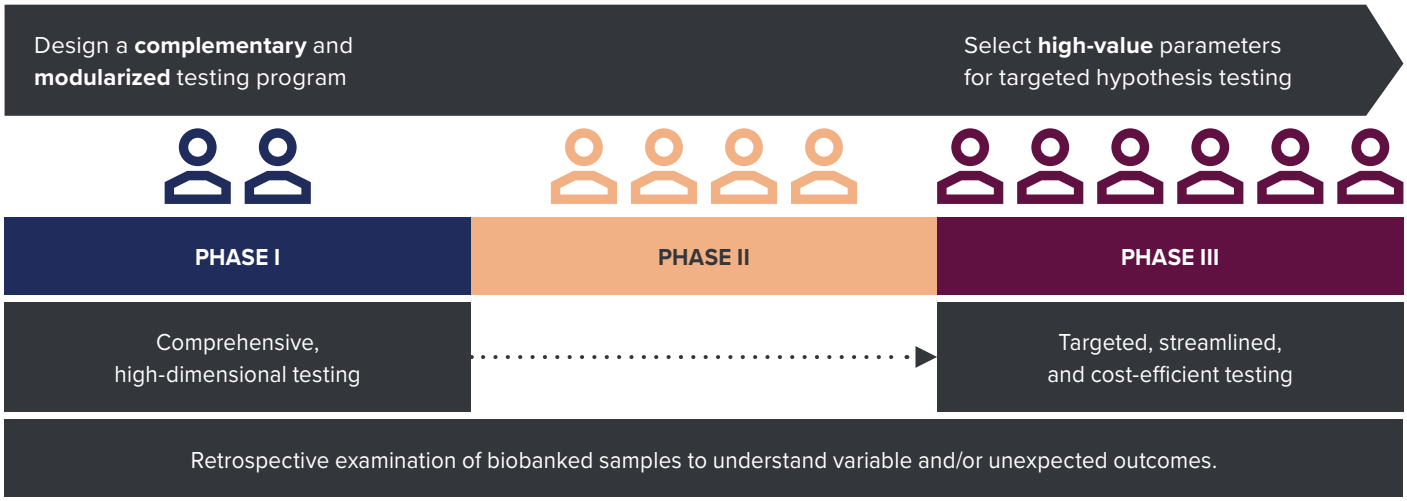


Figure 2: A framework to plan, design, and deploy clinical testing programs for new cell therapies.

The design of such adaptive testing programs **builds on three strategies**. First, **complementary testing methods** are used to capture a comprehensive picture of a cell therapy candidate without overly amassing assays in a testing program. Second, **testing programs are modularized** so certain parameters can be measured with non-customized, off-the-shelf assays. Finally, each readout is assessed to **select those with the greatest value** in characterizing a candidate based on insights, clinical phase, and testing costs. That selection can be used to simplify testing in the same program, determine the relevance of a readout for alternative settings, or identify instances where banking samples for retrospective testing is warranted.

COMPLEMENTARITY OF METHODS

Leverage synergies between readouts of well-understood testing methods to deliver comprehensive evaluation.

MODULARITY IN DEPLOYMENT

Identify aspects in a testing program that can be addressed with standardized, off-the-shelf analytics.

VALUE OF READOUT

Assess readouts to select measures with the greatest value or to use existing assays in alternative testing settings.

Additional advantages of adopting these strategies include:

- A good match to study cohort size, with more parameters collected from fewer patients at early stages and selected analytics when cohorts are larger in later stages.
- A path to validate higher endpoint assays during early exploratory testing, possibly coupling biomarkers with traditional endpoints to serve as surrogate endpoints (see *"MRD: a new surrogate endpoint for multiple myeloma"* on page 8).
- An opportunity to expand knowledge about cell therapies and support proof-of-concept studies to validate a testing platform for additional programs and strategies.

The following sections explore five testing areas in the characterization of cell therapies. For each, our experts briefly describe current clinical objectives and established technologies and share thoughts about opportunities to implement the strategies above.

AREA 1.

B-cell aplasia: titrating therapy efficacy and off-tumor effects

- **COMPLEMENTARITY**
  A battery of complementary assays to measure B-cell aplasia helps discriminate on- and off-tumor activity. The parameters monitored in B cell populations will expand as cell therapies address new indications, like autoimmune disease.
- **VALUE**
  A comprehensive understanding of off-tumor effects like depletion of healthy B cells can also inform new assay designs to enhance clinical testing and new therapeutic concepts to improve specificity.

Most of today's approved cell therapies target B cells. With CD19 and BCMA as targets, they do not distinguish between cancerous and healthy B cells. Hence, treated patients develop B-cell aplasia. *"The loss in B cells can be managed clinically,"* says Vervoort, *"and so, must be monitored. In other cancers, off-tumor effects must be averted as eliminating other healthy cells can have devastating effects."*

An assembly of complementary assays generates a comprehensive picture of how therapeutic action impacts B-cell populations, highlighting differences among body tissues and discriminating between on-tumor and off-tumor activity (Table 1).

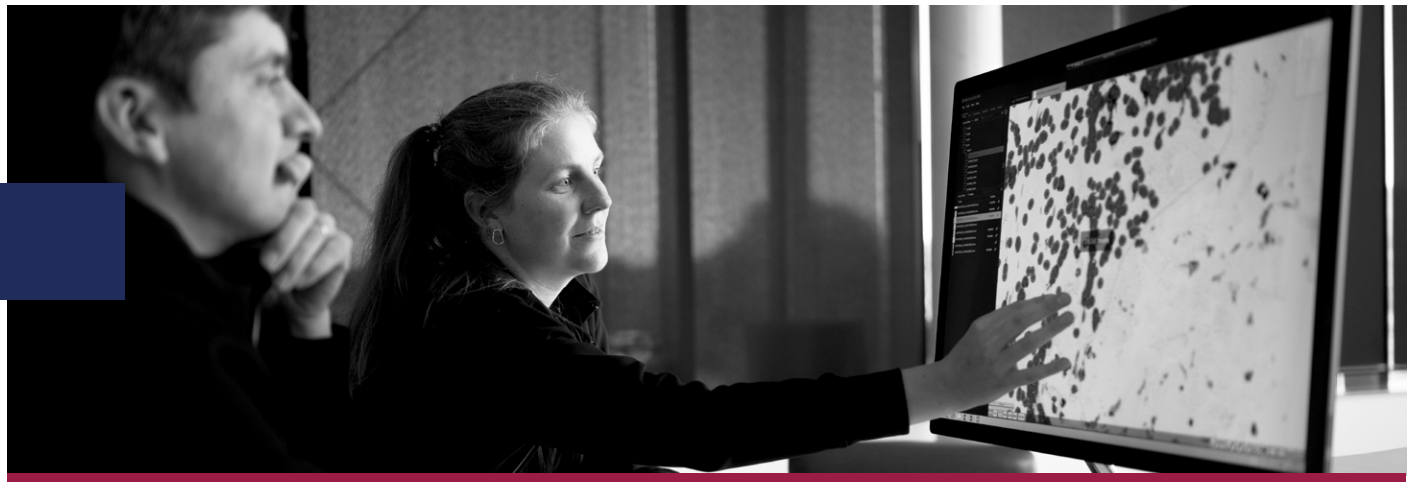
Table 1: Complementary assays used to monitor B cell aplasia.

	B CELL ENUMERATION	TARGET TISSUE ARCHITECTURE	GENOMIC ASSESSMENT	CAR T-CELL ACTIVITY
Method	Flow cytometry	Immunohistochemistry	NGS	Flow cytometry or dPCR
Purpose	Determine extent of aplasia based on absolute B-cell count in peripheral whole blood (# cells/uL of whole blood). Phenotyping of peripheral B cells.	Phenotype B cells at tumor site based on staining of B cell-specific membrane markers. Examine tissue architecture and changes in compartments.	Detect genomic profile switching and instability that can lead to relapse. Measure B-cell aplasia via deconvolution algorithms and/or BCR sequencing.	Assess results from complementary readout on B cells in the context of therapy activity.

Vervoort expects B-cell monitoring to be part of testing programs for new cell therapies and indications. Which assays are included in a program depends on the value of readouts for a given clinical objective. A fast and unambiguous enumeration of B cells to report on general patient immune health can inform study inclusion. Conversely, comprehensive reporting can support novel contexts. For example, assessing the B-cell depletion levels that eliminate autoreactivity and monitoring the recovery and clonality of memory B-cell populations is relevant to understanding the therapeutic value of anti-CD19 CAR T cells for autoimmune diseases.[4]

New assays may also emerge to expand the current toolbox for B-cell aplasia monitoring and serve complementary purposes. Already today, M-protein quantification is used as a proxy measure of malignant B-cell prevalence in multiple myeloma (see *"MRD: A new surrogate endpoint for multiple myeloma"* on page 8).

Finally, experience measuring B-cell aplasia also informs new therapy development. Especially when a target is expressed in non-target tissues, initial studies will need to titrate cell therapy activity with off-tumor effects. Vervoort adds: *"Developers are already designing new constructs with logic gating[5] to circumvent this problem and enhance tumor specificity."*



MRD: A NEW SURROGATE ENDPOINT FOR MULTIPLE MYELOMA

Minimal residual disease (MRD) correlates with traditional clinical endpoints in multiple myeloma (MM) and is measured via flow cytometric and sequencing analysis of bone marrow aspirates or mass spectrometric (MS) analysis of blood to quantify M-protein produced by malignant plasma cells. The FDA has approved MRD as a surrogate endpoint in myeloma clinical trials to accelerate new drug approvals.[6] One study showed that on average, MS-based quantification of M-protein detects disease progression more than a year earlier than using methods according to criteria of the International Myeloma Working Group.[7] Our experts anticipate changes to trial designs with MRD used to report on tumor shrinkage, stratify patients, and inform decisions about treatment intensification or switching.

Aiming to establish a robust and accelerated clinical assessment of MRD, CellCarta is developing a high-resolution examination of M-protein signatures to include:

- Tracking signature changes over time
- Examining clonality and its evolution under therapeutic pressure
- Complementing readouts with flow cytometry reports on B cells

A better understanding of how M-protein changes over time in the context of B cell population dynamics and clonality can help anticipate disease changes and adapt treatment accordingly. As stated in a recent study published in Blood Cancer Journal (Noori et al. 2024): *"Dynamic MS-MRD monitoring in retrospective and prospective patient cohorts will enable defining progression in a reliable way and has likely complementary value in MM patients with extramedullary disease."*[7]

AREA 2.

Cell enumeration and vector copy number (VCN): monitoring from different angles

- **COMPLEMENTARITY**
  Cell enumeration and VCN determination use different analytes to measure cell therapy expansion. When aligned, VCN can serve as a proxy measure of cell number.
- **VALUE**
  Rising diversity of cell therapies requires customized flow cytometry panels and dPCR amplification targets. Identifying off-the-shelf assays with universal reagents or generic detection targets builds modular testing programs that are quick to deploy. Similarly, modular data analytics streamline readouts and standardize interpretation.

Cell enumeration and vector copy number (VCN) determination are complementary methods that measure the abundance and persistence of therapeutic cells from different angles (Table 2). While cell counts are based on flow cytometric detection of surface proteins, VCN is the PCR-based quantification of constructs transduced into a cell. In early-phase trials, cell and vector frequencies are augmented with *"multiplex flow cytometry assays,"* describes Hanafi. *"Capturing several biomarkers lets you monitor the polyfunctionality of complex therapy constructs or the different cell types responding to a therapy."*

Critically, alignment between the two measures lends high confidence in the interpretation of therapy expansion and persistence data and allows the use of logistically simpler VCN measures as a proxy of cell enumeration in later-phase trials (Table 2).

Table 2: Cell enumeration, and VCN.

	CELL ENUMERATION	VECTOR COPY NUMBER (VCN)
Method	Flow cytometry	dPCR
Analyte	Surface proteins	DNA
Early phase	■ Demonstrate that construct is being expressed on cell surface ■ Provide information about which cell types are expressing the construct, their status and phenotype (e.g., activated, repressed) ■ Confirms that the construct is not expressed in unwanted cells **First in Human Trials** ■ Reveals any bystander effect, like activation of endogenous cells ■ Track path of therapeutic cells to target tumor	■ Demonstrate that VCN per cell is <5 to reduce risk of cytokine release syndrome (CRS)
Late phase	■ Advantage of combining enumeration with phenotyping markers ■ Limited use because of complex sample collection and transportation to off-site laboratories and difficult scale-up ■ Omitted when a correlation with VCN is established in early phase studies	■ A sensitive method for long-term monitoring ■ Collection of samples (peripheral blood, bone marrow, cerebrospinal fluid) requires less handling

Hanafi shares that cell therapies entering clinical stages are shifting demand toward customized cell enumeration and VCN assays, which are time and resource-consuming to develop and validate. She anticipates that the small number of CAR-specific anti-idiotypes used to enumerate today's cell therapies will balloon as therapeutic targets diversify and grow in number. Similarly, VCN assays will be customized to track proprietary constructs, an important trend as the likelihood increases that patients receive more than one cell therapy.

New sample types will also drive customization. Therapeutic cells, like CAR-macrophages, may not be found in circulating blood, and novel antigen targets will need to be monitored in various tissues. Thus, peripheral and other tissue types will be collected and analyzed using dedicated protocols.

One option to minimize the impact of assay customization is to modularize testing programs by identifying generic test analytes. For example, CellCarta quantifies the commonly used transgene promoter woodchuck hepatitis virus posttranscriptional regulatory element (WPRE) to measure VCN. Our off-the-shelf assay is quick and easy to deploy.

"In a comparable strategy," says Hanafi, *"we are exploring global assays for some of the unique features in cells of next-generation therapies. A universal detection reagent for CAR-based therapies would be advantageous for flow cytometry where customization can be time-consuming."*

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Another option is to modularize the analysis of flow cytometry data. Our team uses auto-gating tools and automated algorithms to standardize common analysis workflows and eliminate operator variability. Hanafi expects these modular analyses to speed up data processing for clinical testing using high-dimensional technologies like spectral flow cytometry.

AREA 3.

HLA typing: new uses for an established diagnostic tool

- **MODULARITY**
  In an evolving regulatory environment, HLA typing assays may become an off-the-shelf option for cell therapy clinical testing.
- **COMPLEMENTARITY**
  Complementary technologies like flow cytometry, immunohistochemistry, and epigenetic testing will expand the relevance of HLA profiling to other therapeutic scenarios.

Though originally developed and validated for donor-recipient matching in stem cell transplantation, HLA typing assays are used in the clinical evaluation of many T-cell receptor (TCR)-based cell therapies. Patients in clinical trials are often stratified by HLA type to ensure the correct match between HLA-peptide complex and the engineered TCR. The selection increases the likelihood of target engagement, improves patient stratification, and ultimately helps accelerate approval timelines.

"HLA typing at CellCarta is done with a 6-loci NGS assay to characterize the complex combination of genes that code HLA polymorphism," describes Dr. Nathalie Bernard, Scientific Business Director at CellCarta. *"The small panel runs quickly and cost-effectively on a small sequencer, and the high coverage of NGS detects even low-frequency sequence differences and discriminates cis and trans configurations."*

The panel is an example of how modularity could streamline testing before and during clinical trials. Bernard explains that the assay is not developed *de novo* for each testing program. HLA genotype is invariant, and the assay is robust. Currently, however, applying the panel to evaluate a cell therapy must be validated for the allele selected. But this may change. Regulators and sponsors are discussing flexibility in using existing HLA typing assays in trials of TCR-based therapies.[8] Pending that decision, a generally validated, off-the-shelf HLA typing assay could be quickly deployed for all testing programs.

In the near future, alternative and complementary assay technologies may expand the relevance of HLA profiling to the characterization of immune evasion in solid tumors and the evaluation of allogeneic approaches. For the first, flow cytometry and immunohistochemistry can monitor the loss of HLA expression by tumor cells, and epigenetic testing can detect locus-specific modifications that suppress HLA expression. For the latter, the safety of off-the-shelf approaches benefits from HLA matching, just as transplantations do.

AREA 4.

Cytokine profiling: showing therapy engagement and activity

- **COMPLEMENTARITY**
  Cell therapy dosing levels are optimized using a complement of assays, including cytokine profiling, VCN determination, and cell enumeration and phenotyping.
- **VALUE**
  High-value signatures selected from comprehensive cytokine profiling in early-phase trials will help characterize the impact of immune health on cell therapy efficacy.

Senior Director of Scientific Business Development at CellCarta, Dr. Nick Dupuis, defines cytokine profiling as a *"report on the pharmacodynamic aspects of a cell therapy focused on changes in cytokine levels elicited by target engagement and the ensuing antitumor activity."*

Deployed in early clinical phases, cytokine profiling can provide insight into adverse effects like cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS).

Used in conjunction with other assays, Dupuis explains, cytokine profiling can also help answer questions about cell therapy administration. *"The FDA project Optimus[9] promotes using cytokine profiling with cell enumeration, cell phenotyping, and VCN determination to identify dosing levels that elicit the desired expansion of therapeutic cells and downstream cytokine activity rather than defaulting to the maximum tolerable dose."*

"Regardless of cell therapy modality, broad-spectrum cytokine profiling at early stages will continue to be a critical assessment. The tools will get better, as will our understanding of the resulting data."

Common platforms for cytokine profiling differ in detection signal and advantages for various testing scales and hypotheses (Table 3). However, they all build on the sandwich immunoassay principle. While many technological developments focus on increasing detection sensitivity,[7,8] Dupuis says, *"immunoassay technologies still dominate because speed and cost-efficiency remain key criteria for clinical testing."*

Table 3: Immunoassay platforms commonly in cytokine profiling.

	MESO SCALE DIAGNOSTICS	OLINK	ELLA
Detection signal	Electrochemiluminescence	Amplicon amplification	Fluorescence
Advantages	■ Widely used ■ High sensitivity	■ High throughput ■ High-plexed discovery mode allows early exploration and transition to targeted low-plex assays using the same antibodies	■ High throughput ■ Fast, sensitive ■ Highly automated ■ Clinically oriented

Dupuis anticipates a vital role for cytokine profiling in assessing novel secondary mechanisms of next-generation construct designs, like CAR T-cell armoring.[10] Every element added to a construct requires a biomarker or signature to show that it works as planned.

Understanding how patient health impacts therapy efficacy is also crucial for therapies approved as earlier-line treatments that operate in the context of a less depleted immune system.

He also describes an emerging application in understanding baseline cytokine signatures that correlate with clinically relevant parameters like maximum cell expansion (C_{max}), adverse events, and therapy resistance. These signatures can reveal how a patient's immune status influences the quality and action of cell therapy (*"What is T-cell fitness, and what dictates it?"* on page 13), and answers could have far-reaching impacts. Studies have shown, for example, that certain cell subpopulations in pre-treatment apheresis material are associated with good cell expansion.[11] Access to those subpopulations may improve starting material for cell product manufacturing but depends on immune status.

Understanding how patient health impacts therapy efficacy is also crucial for therapies approved as earlier-line treatments that operate in the context of a less depleted immune system. Finally, correlations with CRS could inform treatment management to medically dampen the reaction with drugs like the anti-IL-6 antibody tocilizumab.[12]

Identifying and validating these cytokine signatures will require early-phase examination of broad-spectrum cytokine profiles. Then, hypotheses about selected high-value parameters can be tested in later phases with larger patient populations. *"We are at the tip of the iceberg with Carl June's publication on CRS,[13]"* says Dupuis. *"Regardless of cell therapy modality, broad-spectrum cytokine profiling at early stages will continue to be a critical assessment. The tools will get better, as will our understanding of the resulting data."*

WHAT IS T-CELL FITNESS, AND WHAT DICTATES IT?

T-cell fitness is the ability to generate an appropriate immune response following stimulation and can profoundly affect responses to immune therapy. T-cell fitness is typically a composite of the frequencies and status of multiple T-cell subpopulations and therefore requires multi-omic analysis to establish.

Cytokine profiling, single-cell multi-omic analysis, and other high-dimensional methods can reveal robust signatures of T-cell health to anticipate or even engineer:

- Changes in T-cell health of patients that promote the efficacy of cell therapies
- Improved quality of starting cellular materials used in cell therapy manufacturing
- The successful activation of a cell therapy in depleted and healthier host immune systems
- Bystander involvement of the host's immune system in anti-tumor activity

AREA 5.

Single-cell analytics: finding better predictors

- **COMPLEMENTARITY**
  Assay technologies that offer single-cell resolution can probe population, genomic, proteomic, and transcriptomic features of cells to characterize cell therapies in early-phase and retrospective studies.
- **VALUE**
  High-value predictive biomarkers of efficacy and safety are identified for more targeted hypothesis testing.

Single-cell analysis technologies are varied and complementary. They probe various information levels in cells to capture a complete picture of cell therapy action. Such analyses can evaluate starting material, characterize a cell product, or monitor both product and host immune system activity at different time points. *"Regardless of application,"* says Dr. Matt Clutter, Director of R&D and Data Analysis at CellCarta, *"single-cell analyses mine a broad range of parameters to find biomarkers or combinations of biomarkers that predict efficacy and safety."*

Several technologies offer single-cell resolution in measuring increasingly large parameter sets. Flow cytometry measures a handful of features on individual cells, while CyTOF and spectral flow cytometry expand that parameter space several fold. Single-cell multi-omic analysis using DNA-barcoded detection reagents and phenotyping antibodies compiles thousands of data points on genomic, transcriptomic, and surface markers at the single cell level. These kinds of readouts have led to the discovery of sought after biomarkers that predict efficacy, resistance and adverse effects.

With increasingly detailed readouts, however, comes a significant time investment in analyzing and interpreting results. Clutter shares: *"There is a choice between measuring a large number of parameters and spending months analyzing them or focusing on a few parameters but therefore knowing their meaning almost in real-time."*

These kinds of readouts have led to the discovery of sought after biomarkers that predict efficacy, resistance and adverse effects.

High costs and complex data analysis make single-cell analyses most impactful in early-phase and retrospective studies. Here, as well, analyses in initial clinical trials identify biomarkers to test with less complex and inexpensive methods in later-phase trials or to elucidate the biology of therapeutic cells in their human hosts. Moreover, retrospective studies can use deep 'omic approaches to inspect banked samples from clinical trials where outcomes were varied or unexpected.

With increasingly detailed readouts, however, comes a significant time investment in analyzing and interpreting results.

The utility of single-cell analytics drives developments to decrease analysis costs and increase the number of cells that can be analyzed. However, truly disruptive change will come in data analytics, says Clutter. Some areas of progress he foresees include:

- Artificial intelligence methods and structural modeling will predict the repertoire of antigen specificities of infused and endogenous T-cells in a patient based on an inventory of TCR sequences. Changes in that repertoire and in TCR clonotype frequencies may correlate with therapy outcomes and reveal bystander effects like epitope spreading.
- Novel analytics that mine large datasets. Initially, these analytics will point to patterns in data for deeper investigation, but further advances may support interpretation in a biological context.
- Strategies for data normalization and integration will make results comparable across clinical studies and, thus, accelerate clinical testing.

Expertise and preparedness to operate in a rapidly evolving field

The future of cell therapies will feature rapid development cycles, with new therapies reaching clinical stages faster than they can be evaluated in trials. Clinical testing plays an important role in narrowing that misalignment. To that end, testing programs must be responsive to the fluidity of the field and contribute to shortening approval timelines.

CellCarta tackles this challenge by constantly examining how existing and new methods can be leveraged to deliver desired readouts. As Bernard describes, *"Every step in cell therapy brings new information. The field changes very rapidly. It's impossible to foresee how the complete ecosystem of cell therapies will evolve, but we can anticipate trends and adapt."*

So, our teams understand new testing demands and apply methods that generate meaningful readouts for a comprehensive picture of cell therapy action and host response. They emphasize preparedness in adopting new methods as they gain broad clinical acceptance and incorporate them into testing programs where they augment value and shorten turnaround time. Finally, they innovate to adapt methods, optimizing trade-offs in testing breadth and efficiency through the standardization and automation of processes and the development of relevant "off-the-shelf" assays.

With a finger on the pulse of the field, our experts are in a unique position to guide clinical testing in an ever-changing landscape and imagine new ways to support the advancement of cell therapies.

Could your cell therapy program benefit from expert support? Find out how we could support you. **Discover more**.

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CellCarta

ABOUT CELLCARTA

Leading provider of specialized precision medicine laboratory services to the biopharmaceutical industry. Leveraging its integrated analytical platforms in immunology, histopathology, proteomics and genomics, as well as related specimen collection and logistics services, CellCarta supports the entire drug development cycle, from discovery to late-stage clinical trials. The company operates globally with 9 facilities located in Canada, USA, Belgium, Australia and China.

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